ТОВ «Б. БРАУН МЕДІКАЛ УКРАЇНА»

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LLC «B. BRAUN MEDICAL UKRAINE»

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Вих. № 1352
від 04.08.2025

Державній службі України
з лікарських засобів
та контролю за наркотиками

Компанія ТОВ «Б. Браун Медікал Україна», яка є Уповноваженим представником легального виробника медичних виробів «Aesculap AG», Німеччина, в Україні, висловлює Вам свою повагу та звертається з інформацією щодо медичного виробу **SKULL TRACTION TONG LARGE**, артикул **FF870R**.

Виробником надано первинний звіт з безпеки Field Safety Notice та FSCA 295 від 01.08.2025, в якому йдеться про наступне:

Виробник проактивно видає це термінове повідомлення про безпеку (FSN), щоб повідомити Вас про оновлені інструкції з використання медичного виробу SKULL TRACTION TONG LARGE (FF870R).

Інформація про Виріб

Виріб використовується при переломах одонтоїда з нежиттєвою дислокацією. Вона забезпечує тимчасову іммобілізацію та/або репозицію в перехідній зоні нестабільного ушкодження шийного відділу хребта, а також для декомпресії спинного мозку або корінців нервів, спричиненої зміщенням хребта.

Опис проблеми

Було встановлено, що інструкція з використання (IFU) не містила важливої інформації щодо протипоказань та деталей застосування. Внаслідок цього критична інформація не була доступна кінцевому користувачеві.

Небезпека, що спричинила ініціювання FSCA

Якщо виріб використовується всупереч зазначеним протипоказанням, існує ризик травмування кістки черепа, твердої мозкової оболонки або навіть тканини головного мозку. Крім того, необхідна сила тяги може не бути досягнута, або прикладена сила може раптово зменшитися під час використання. Це призведе до повторного стиснення хребців і, можливо, нервів у місці прикріплення штифтів.

Контактні дані:
Михайлюк М.С.
+380671553531

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Передбачений ризик для пацієнтів/користувачів

Існує потенційний ризик для пацієнтів у разі неправильного використання виробу. Неналежне застосування може призвести до травм у ділянці кістки черепа та твердої мозкової оболонки. Внаслідок цього може виникнути кровотеча, яка, своєю чергою, може спричинити тимчасові або постійні неврологічні порушення. Крім того, неправильне застосування може призвести до подовження процедури або завдати додаткової шкоди пацієнту, наприклад, зсуву або переміщення штифтів. Додаткові травми також можуть виникнути, якщо тягарі для тракції не застосовуються поступово та рівномірно. Щоб мінімізувати ці ризики, після кожного коригування ваги слід проводити візуалізацію, оскільки це відповідає встановленій стандартній процедурі для такого типу лікування.

Передача цієї інформації

Виробник звертається з проханням передати це повідомлення про безпеку всім відповідним особам у межах компанії, а також до будь-якої організації, куди могли бути передані потенційно уражені вироби SKULL TRACTION TONG LARGE.

Дії з боку ТОВ «Б. Браун Медікал Україна»

Інформація по безпеці була передана клієнту.

У разі отримання доповнень чи додаткової інформації від виробника нами буде надано оновлення до першого звіту.

Додатковий матеріал: 16 стор.

З повагою,

Керівник структурного підрозділу із стандартизації, сертифікації та реєстрації — Чернега О.В.

Фахівець з фармаконагляду — Михайлюк М.С.

Контактні дані:
Михайлюк М.С.
+380671553531

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FSCA Ref: 295

Date/Datum: 2025-08-01

Urgent Field Safety Notice/Dringende Sicherheitsinformation (FSN)
SKULL TRACTION TONG LARGE – FF870R
Schädelhalter Gross – FF870R

For Attention of: **Users, Importers and Distributors of the affected products.**
Zu Beachtung für: **Anwender, Importeure und Distributoren der betroffenen Produkte.**

Contact details of local representative (name, e-mail, telephone, address etc.) Kontaktdaten des lokalen Vertreters (Name, E-Mail, Telefon, Adresse usw.)
Aesculap AG **Quality Management** **Postfach 40** **78501 Tuttlingen** **Germany/Deutschland** **Quality Management** Contact Point/Ansprechpartner: Dominik Neumeister FSCA Coordinator Phone/Telefon: +49 7461-95 31139 Mail/E-Mail: vigilance_aag.de@aesculap.de **Global Marketing** Contact Point/Ansprechpartner: Alexander Kerle Product Manager Global Marketing Phone/Telefon: +49 1752776532 Mail/E-Mail: alexander.kerle@aesculap.de

Dear Customer,

Aesculap AG, as the legal manufacturer of the affected product, is proactively issuing this urgent Field Safety Notice (FSN) to inform you about the updated instructions for use of our SKULL TRACTION TONG LARGE (FF870R).

Geschätzter Kunde,

die Aesculap AG, als rechtlicher Hersteller des betroffenen Produkts, veröffentlicht präventiv diese dringende Sicherheitsinformation (FSN), um Sie über die aktualisierte Gebrauchsanweisung zur Verwendung unserer Schädelhalter Gross (FF870R) zu informieren.

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1. Information on Affected Devices/Angaben zu den betroffenen Produkten	
1.1	**Device Type(s) / Produktgruppe(n)**
	SKULL TRACTION TONG LARGE *SCHÄDELHALTER GROSS*
1.2.	**Commercial name(s) / Handelsname(n)**
	SKULL FIXATION
1.3.	**Unique Device Identifier(s) / Eindeutige Gerätebezeichnung (UDI-DI)**
	403923900000290738
1.4.	**Primary clinical purpose of device(s) / Primärer klinischer Nutzen der Produkte**
	The skull traction tong is used for odontoid fractures with non-lethal dislocation. It provides temporary immobilization and/or reduction in the transitional region of an unstable cervical spinal injury, as well as for de-compression of the spinal cord or nerve roots secondary to spinal misalignment. *Der Schädelhalter wird bei Frakturen des Os odontoideum mit nicht-letaler Dislokation verwendet. Er dient zur temporären Immobilisierung und/oder Reposition im Übergangsbereich einer instabilen Halswirbelsäulenverletzung sowie zur Dekompression des Rückenmarks oder der Nervenwurzeln infolge einer Fehlstellung der Wirbelsäule.*
1.5	**Device Model/Catalogue/part number(s) / Gerätemodell/Katalog/Artikelnummer(n)**
	FF870R
1.6	**Software version / Software Version**
	N/A
1.7	**Affected serial or lot number / Betroffene Serien- oder Chargennummern**
	N/A
1.8	**Associated devices / zugehörige Produkte**
	N/A

2. Reason for Field Safety Corrective Action/Grund für die Sicherheitskorrekturmaßnahme (FSCA)	
2.1	**Description of the product problem / Problembeschreibung**
	It was identified that the Instructions for Use (IFU) did not include essential information regarding contraindications and application details. As a result, this critical information was not made available to the end user. *Es wurde festgestellt, dass die Gebrauchsanweisung (IFU) wesentliche Informationen bezüglich der Kontraindikationen und Anwendungsdetails nicht enthielt. Infolgedessen standen diese kritischen Informationen dem Endbenutzer nicht zur Verfügung.*
2.2	**Hazard giving rise to the FSCA / Gefahr, der Anlass für die FSCA ist**
	If the product is used in contradiction to the stated contraindications, there is a risk of injury to the skull bone, dura mater, or even brain tissue. Additionally, the necessary traction force may not be achieved, or the applied force may suddenly decrease during use. This would result in the vertebrae and possible nerves being compressed again at the area where the pins are attached. *Wird das Produkt entgegen den angegebenen Kontraindikationen verwendet, kann es zu Verletzungen des Schädelknochens, der Dura mater oder sogar des Gehirngewebes kommen. Zudem besteht die Gefahr, dass die erforderliche Zugkraft nicht erreicht wird oder dass die aufgebrachte Zugkraft während des Vorgangs plötzlich nachlässt. Dies kann dazu führen, dass die Wirbel sowie möglicherweise angrenzende Nerven an der Stelle der Pin-Fixierung erneut komprimiert werden.*

2.3	**Probability of problem arising / Auftretenswahrscheinlichkeit des Problems**
	Within the past five years (10.2019-06.2025) no complaints were registered. This results in a failure rate of 0 ppm. *Innerhalb der letzten fünf Jahre (10.2019-06.2025) wurden keine Reklamationen registriert. Daraus ergibt sich eine Fehlerrate von 0 ppm.*
2.4	**Predicted risk to patient/users / Risiko Prognose für Patienten/Endanwender**
	There is a potential risk to patients if the product is not used correctly. Improper use can lead to injuries in the area of the skull bone and the dura mater. A resulting hemorrhage could lead to temporary or permanent neurological damage. Additionally, incorrect application may prolong the procedure or cause further harm to the patient, such as pin displacement or movement. Further injuries can also occur if the traction weights are not applied gradually and evenly. To minimize these risks, imaging should be performed after each weight adjustment, as this reflects the established standard procedure for this type of treatment. *Für Patienten besteht ein potenzielles Risiko, wenn das Produkt nicht sachgemäß angewendet wird. Eine unsachgemäße Nutzung kann zu Verletzungen im Bereich des Schädelknochens und der Dura mater führen. Eine daraus resultierende Blutung könnte vorübergehende oder dauerhafte neurologische Schäden zur Folge haben. Darüber hinaus kann eine fehlerhafte Anwendung den Eingriff verlängern oder zusätzliche Verletzungen verursachen, etwa durch ein Verrutschen oder eine Fehlpositionierung der Pins. Weitere Schäden können entstehen, wenn die Zuggewichte nicht gleichmäßig und in kleinen Schritten aufgebracht werden. Zur Minimierung dieser Risiken sollte nach jeder Gewichtsanpassung eine bildgebende Kontrolle der Traktion erfolgen, da dies dem etablierten Standardverfahren entspricht.*
2.5	**Further information to help characterise the problem / Weitere Informationen zur Charakterisierung des Problems**
	N/A
2.6	**Background on Issue / Hintergrund zu dem Problem**
	N/A
2.7	**Other information relevant to FSCA / Weitere relevante Informationen zur FSCA**
	N/A

	3. Type of Action to mitigate the risk / Art der Maßnahme zur Minderung des Risikos
3.1	**Action To Be Taken by the User / Vom Anwender zu ergreifender Maßnahme**
	The Instruction for Use (IFU) TA009782 has been updated (Change No. AE0065363) accordingly with the following changes in content: **2.1.2 Intended use** The skull traction tong is used for odontoid fractures with non-lethal dislocation. It provides temporary immobilization and/or reduction in the transitional region of an unstable cervical spinal injury, as well as for de-compression of the spinal cord or nerve roots secondary to spinal misalignment. **2.1.4 Absolute contraindications** - Patients with open fontanelles - Malformations or known reduction of the bone tissue, in particular temporal bone malformations

	2.1.5 Relative contraindications The following conditions, individual or combined, can lead to delayed healing or compromise the success of the operation: - Medical or surgical conditions (e.g., comorbidities) that could hinder the success of the operation. - Children less than 5 years of age - Patients with local sepsis - Patients who are not awake, alert, and cooperative - Skull fractures and particular cervical spine injuries (in particular unstable injuries rostral to the target level, traumatic disc herniations and definitive, complete ligamentous injuries at any cervical spine level). In the presence of relative contraindications, the user decides individually regarding the use of the product. ***Die Gebrauchsanweisung (IFU) TA009782 wurde entsprechend mit den folgenden inhaltlichen Änderungen (Änderung Nr. AE0065363) aktualisiert:*** ***2.1.2 Bestimmungsgemäße Verwendung*** *Der Schädelhalter wird bei Frakturen des Os odontoideum mit nicht-letaler Dislokation verwendet. Er dient zur temporären Immobilisierung und/oder Reposition im Übergangsbereich einer instabilen Halswirbelsäulenverletzung sowie zur Dekompression des Rückenmarks oder der Nervenwurzeln infolge einer Fehlstellung der Wirbelsäule.* ***2.1.4 Absolute Kontraindikationen*** *- Patienten mit offenen Fontanellen* *- Fehlbildungen oder bekannte Reposition des Knochengewebes, insbesondere temporale Knochenfehlbildungen* ***2.1.5 Relative Kontraindikationen*** *Die folgenden Bedingungen, individuell oder kombiniert, können zu verzögerter Heilung bzw. Gefährdung des Operationserfolges führen:* *- Medizinische oder chirurgische Zustände (z. B. Komorbiditäten), die den Erfolg der Operation verhindern könnten.* *- Kinder bis 5 Jahre* *- Patienten mit lokaler Sepsis* *- Patienten, die nicht wach, aufmerksam und kooperativ sind* *- Schädelfrakturen und bestimmte Verletzungen der Halswirbelsäule (insbesondere instabile Verletzungen rostral zur Zielebene, traumatische Bandscheibenhernien und definitive, vollständige Bänderverletzungen auf jeder Ebene der Halswirbelsäule).* *Bei relativen Kontraindikationen entscheidet der Anwender individuell über die Verwendung des Produkts.*	
3.2	**By when should the action be completed?** **Bis wann muss die Maßnahme abgeschlossen sein?**	The Aesculap AG plans to complete this FSCA within the next 9 months. *Die Aesculap AG plant diese FSCA innerhalb der nächsten 9 Monate abzuschließen.*
3.3	**Is follow-up of patients or review of patients' previous results recommended?** **Wird eine Nachsorge der Patienten oder eine Überprüfung der früheren Ergebnisse der Patienten empfohlen?**	
	No / *Nein*	

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3.4	**Is customer reply required?** **Ist eine Antwort des Kunden erforderlich?**	Yes. See point 4.3 Ja. Siehe Punkt 4.3
3.5	**Action Being Taken by the Manufacturer / Vom Hersteller ergriffene Maßnahme** The new eIFU will be published from 01th August 2025 at https://eifu.bbraun.com *Die neue eIFU wird am 01. August 2025 veröffentlicht unter: https://eifu.bbraun.com*	
3.6	**Is the FSN required to be communicated to the patient /lay user?** **Muss die FSN dem Patienten/Laienbenutzer übermittelt werden?**	No Nein
3.7	**If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?** **Falls ja, hat der Hersteller zusätzliche Informationen für den Patienten/Liegenutzer in einem Informationsschreiben/Blatt für den Patienten/Liegenutzer oder den nicht berufsmäßigen Nutzer bereitgestellt?**	
	N/A	

	4. General Information* / Allgemeine Informationen*	
4.1	**FSN Type / FSN Typ**	New / Neu
4.2	**Manufacturer information** (For contact details of local representative refer to page 1 of this FSN) ***Angaben zum Hersteller*** *(Die Kontaktdaten des Herstellers finden Sie auf Seite 1 dieses FSN)*	
	Company Name/Name des Unternehmens	Aesculap AG
	Address/Adresse	Postfach 40, 78501 Tuttlingen
	Website address/Homepage	http://www.aesculap.de
4.3	**List of attachments/appendices:** **Liste der Anlangen/Anhänge:**	Feedback Form *Rückmeldeformular*
4.4	**Name/Signature/Unterschrift**	
		Jacqueline Liebers Person Responsible for Regulatory Compliance (PRRC) Quality Management
	Name/Signature/Unterschrift	
		Christian von der Grün Director Post Market Surveillance Quality Management

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	Transmission of this Field Safety Notice/Übermittlung dieses Sicherheitshinweises (FSN)
	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. 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. *Dieser Hinweis muss an alle Personen in Ihrem Unternehmen übermittelt werden oder an alle Unternehmen/Einrichtungen, wohin die eventuell betroffenen Produkte geliefert wurden (wie jeweils zutreffend).* *Bitte leiten Sie diesen Hinweis an andere Unternehmen/Einrichtungen weiter, auf die diese Maßnahme Auswirkungen hat (wie jeweils zutreffend).* *Bitte sorgen Sie über einen angemessenen Zeitraum dafür, dass dieser Hinweis berücksichtigt wird und bekannt ist, um die Wirksamkeit der Korrekturmaßnahme zu gewährleisten.* *Bitte melden Sie dem Hersteller, Händler oder lokalen Vertreter sowie gegebenenfalls der zuständigen nationalen Behörde alle Vorfälle im Zusammenhang mit dem Produkt, da dies eine wichtige Rückmeldung darstellt.*

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? medizinprodukte@bfarm.de; medizinprodukte@basg.gv.at; vigilance.meddev@fagg-afmps.be; todor.darakchiev@bda.bg ; bda@bda.bg; psvigilancia@aemps.es; materiovigilance@ansm.sante.fr; vigilancematerial@eof.gr;dgfdm@postacert.sanita.it ; l. lispi@sanita.it ;vigilance@sanita.it; vaspvt@vaspvt.gov.lt; meddevices.vigilance@ms.etat.lu; info@zva.gov.lv; meldpunt@igj.nl; incydenty@urpl.gov.pl; dvps@infarmed.pt; mdevice@anm.ro; darina.kaminska@sukl.sk
Type of report (•) Initial report ( ) Follow-up report ( ) Final report
Date of this report 2025-08-01
Reference number assigned by the manufacturer FSCA 295
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report
Status of submitter (•) Manufacturer ( ) Authorised Representative within EEA and Switzerland ( ) Others: (identify the role)

3 Manufacturer information	new

Name Aesculap AG	
Contact Name Jacqueline Liebers	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone +49 7461 95 31830	**Fax**
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country** DE - Germany

5 National contact point information

new

National contact point name Aesculap AG	
Name of the contact person Jacqueline Liebers	
Address Postfach 40	
Postcode 78501	**City** Tuttlingen
Phone +49 7461 95 31830	**Fax**
E-mail vigilance_aag.de@aesculap.de	**Country** DE - Germany

6 Medical device information	new

Class

- ○ AIMD Active implants
- ○ MDD Class III
- ○ MDD Class IIb
- ◉ MDD Class IIa
- ○ MDD Class I
- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD Devices for self-testing
- ○ IVD General

Nomenclature system (preferable GMDN)	**Nomenclature code**
GMDN	46528
Nomenclature text	
Traction system skull tongs	
Commercial name/ brand name / make	
SKULL TRACTION TONG LARGE	
Model number	**Catalogue number**
	FF870R
Serial number(s)	**Lot/batch number(s)**
N/A	N/A
Device Mfr Date	**Expiry date**

Notified Body (NB) ID-number
0123
Accessories / associated devices (if applicable)
Software version number (if applicable)

7 Description of the FSCA

Background information and reason for the FSCA

Due to a deficiency report from TÜV SÜD regarding the Technical Documentation, it was identified that the Instructions for Use (IFU) lacked essential information concerning specific indications, contraindications, and application details. As a result, this information was not made available to the end user.

Iff the product is used contrary to the stated contraindications, there is a risk of injury to the skull bone, dura mater, or even brain tissue. Additionally, the necessary traction force may not be achieved, or the applied force may suddenly decrease during use. This would result in the vertebrae and possible nerves being compressed again at the area where the pins are attached.

There is a potential risk to patients if the product is not used correctly. Improper use can lead to injuries in the area of the skull bone and the dura mater. If the product comes into contact with the dura, this may result in temporary or permanent paralysis. Additionally, incorrect application may prolong the procedure or cause further harm to the patient, such as pin displacement or movement. Further injuries can also occur if the traction weights are not applied gradually and evenly. To minimize these risks, imaging should be performed after each weight adjustment, as this reflects the established standard procedure for this type of treatment.

Within the past five years no complaints were registered. This results in a failure rate of 0 ppm.

Description and justification of the action (corrective / preventive)

The Instruction for Use (IFU) has been updated accordingly with the following changes in content:

2.1.2 Intended use
The skull traction tong is used for odontoid fractures with non-lethal dislocation. It provides temporary immobilization and/or reduction in the transitional region of an unstable cervical spinal injury, as well as for de-compression of the spinal cord or nerve roots secondary to spinal misalignment.

2.1.3 Indications
Note
The manufacturer is not responsible for any use of the product against the specified indications or the described applications.
For indications, see Intended use.

2.1.4 Absolute contraindications
- Patients with open fontanelles
- Malformations or known reduction of the bone tissue, in particular temporal bone malformations

2.1.5 Relative contraindications
The following conditions, individual or combined, can lead to delayed healing or compromise the success of the operation:
- Medical or surgical conditions (e.g., comorbidities) that could hinder the success of the operation.
- Children less than 5 years of age
- Patients with local sepsis
- Patients who are not awake, alert, and cooperative
- Skull fractures and particular cervical spine injuries (in particular unstable injuries rostral to the target level, traumatic disc herniations and definitive, complete ligamentous injuries at any cervical spine level).

In the presence of relative contraindications, the user decides individually regarding the use of the product.

Advice on actions to be taken by the distributor and the user

By confirming receipt of the Field Safety Notice, end customers acknowledge that they followthe updated instructions for Use (IFU).

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

Time schedule for the implementation of the different actions

The Aesculap AG plans to complete this FSCA within the next 9 months.

Attached please find	FSN Status
☒ Field Safety Notice (FSN) in English	○ Draft FSN
☐ FSN in national language	◉ Final FSN
☐ Others (please specify)	

The medical device has been distributed to the following countries:

within the EEA and Switzerland

☒ AT	☒ BE	☒ BG	☒ CH	☐ CY	☐ CZ	☒ DE	☒ DK
☐ EE	☒ ES	☐ FI	☒ FR	☒ GB	☒ GR	☐ HU	☐ IE
☐ IS	☒ IT	☐ LI	☒ LT	☒ LU	☒ LV	☐ MT	☒ NL
☐ NO	☒ PL	☒ PT	☒ RO	☐ SE	☐ SI	☒ SK	☒ TR

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

AE, AO, AR, AU, BD, BF, BO, BR, BW, CI, CL, CM, CO, CU, DZ, EG, ET, GA, GE, HK, ID, IN, IR, JO, JP, KE, KR, KW, KZ, LB, LK, LY, MA, MM

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

I affirm that the information given above is correct to the best of my knowledge

print | check | send XML-data by E-Mail

AESCULAP®

en	**Instructions for use/Technical description** Skull traction tong
USA	Note for U.S. users This Instructions for Use is NOT intended for United States users. Please discard. The Instructions for Use for United States users can be obtained by visiting our website at www.aesculapusaifus.com. If you wish to obtain a paper copy of the Instructions for Use, you may request one by contacting your local Aesculap representative or Aesculap's customer service at 1-800-282-9000. A paper copy will be provided to you upon request at no additional cost.
de	**Gebrauchsanweisung/Technische Beschreibung** Schädelhalter
fr	**Mode d'emploi/Description technique** Pince de traction crânienne
es	**Instrucciones de manejo/Descripción técnica** Pinzas de tracción craneal
it	**Istruzioni per l'uso/Descrizione tecnica** Pinze di trazione per cranio
pt	**Instruções de utilização/Descrição técnica** Pinça de tração craniana
nl	**Gebruiksaanwijzing/Technische beschrijving** Schedeltractietang
da	**Brugsanvisning/Teknisk beskrivelse** Kranietang
no	**Bruksanvisning/Teknisk beskrivelse** Trekktang for hodeskalle
sv	**Bruksanvisning/Teknisk beskrivning** Skalltång för traktion
fi	**Käyttöohje/Tekninen kuvaus** Kallovetopihdit
et	**Kasutusjuhend/Tehniline kirjeldus** Kolju haardetangid
lv	**Lietošanas instrukcijas/tehniskais apraksts** Galvaskausa vilces knaibles
lt	**Naudojimo instrukcija/techninis aprašas** Glisono kilpa
ru	**Инструкция по применению/Техническое описание** Захват для вытяжения за череп
cs	**Návod k použití/Technický popis** Trakční lebeční kleště
pl	**Instrukcja użytkowania/Opis techniczny** Klamra wyciągowa
sk	**Návod na použitie/Technický opis** Kliešte na trakciu lebky
hu	**Használati útmutató/Műszaki leírás** Koponya trakciós fogó
sl	**Navodila za uporabo/Tehnični opis** Trakcijske klešče za lobanjo
hr	**Upute za uporabu/Tehnički opis** Hvataljke za povlačenje lubanje
ro	**Manual de utilizare/Descriere tehnică** Cleşte de tracţiune pentru craniu
bg	**Упътване за употреба/Техническо описание** Щипци за тракция на черепа
tr	**Kullanım Kılavuzu/Teknik açıklama** Kafatası traksiyon kıskacı
el	**Οδηγίες χρήσης/Τεχνική περιγραφή** Λαβίδα έλξης κρανίου
br	**Instruções de uso/Descrição técnica** Pinça de tração de crânio

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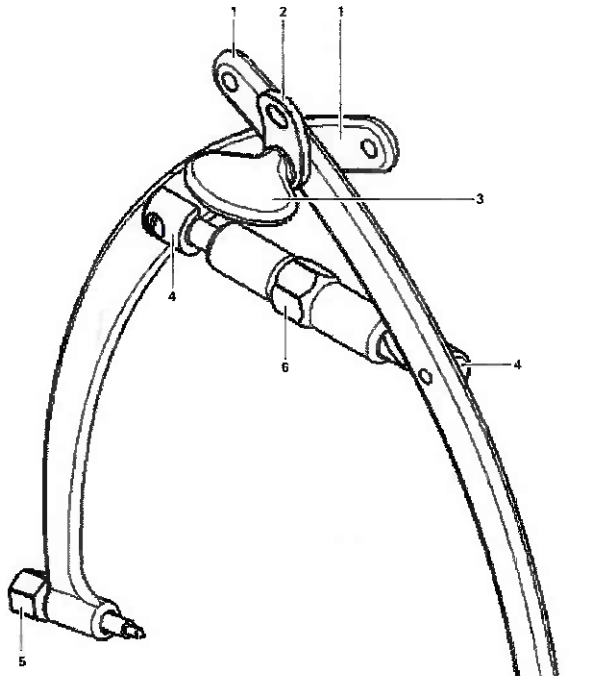

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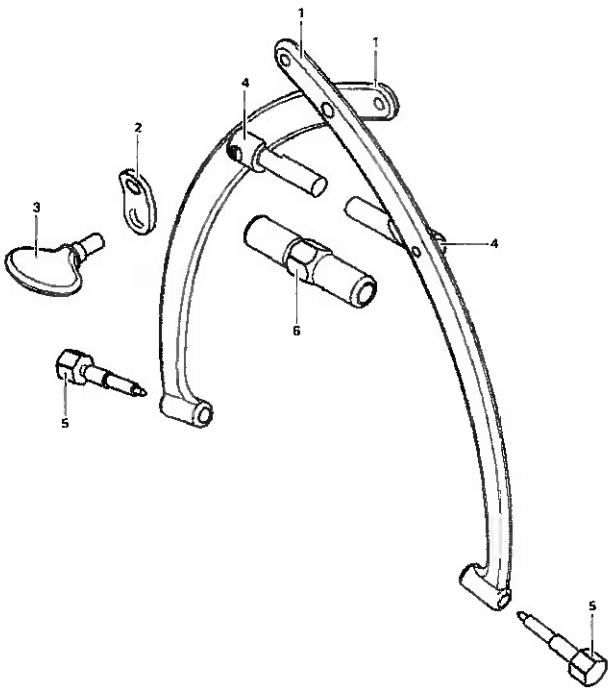

2

en

AESCULAP®

Skull traction tong

Legend

1 Support arm
2 Tension plate
3 Flap screw
4 Joining rod
5 Mandrel screw
6 Spindle screw

1 About this document

Note

General risk factors associated with surgical procedures are not described in this document.

1.1 Scope

This document applies to the following products:

- Skull traction tong
  - FF870R Skull traction tong large

Note

Instructions for use and further information about B. Braun / AESCULAP products can be found on the B. Braun eIFU website at eifu.bbraun.com

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

⚠ WARNING
Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

⚠ CAUTION
Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2 Clinical use

2.1 Areas of use and limitations of use

2.1.1 Intended purpose

Skull traction tong is used for temporary cervical traction of odontoid fractures.

2.1.2 Intended use

The skull traction tong is used for odontoid fractures with non-lethal dislocation. It provides temporary immobilization and/or reduction in the transitional region of an unstable cervical spinal injury, as well as for decompression of the spinal cord or nerve roots secondary to spinal misalignment.

2.1.3 Indications

Note

The manufacturer is not responsible for any use of the product against the specified indications or the described applications.

For indications, see Intended use.

2.1.4 Absolute contraindications

- Patients with open fontanelles
- Malformations or known reduction of the bone tissue, in particular temporal bone malformations

2.1.5 Relative contraindications

The following conditions, individual or combined, can lead to delayed healing or compromise the success of the operation:

- Medical or surgical conditions (e.g., comorbidities) that could hinder the success of the operation.
- Children less than 5 years of age
- Patients with local sepsis
- Patients who are not awake, alert, and cooperative
- Skull fractures and particular cervical spine injuries (in particular unstable injuries rostral to the target level, traumatic disc herniations and definitive, complete ligamentous injuries at any cervical spine level).

In the presence of relative contraindications, the user decides individually regarding the use of the product.

2.1.6 Intended patient population

There are no general gender or ethnic limitations on patient population for the use of the product when used within its intended use. Restrictions are defined by the contraindications.

2.2 Risks, adverse effects and interactions

- pin loosening/moving
- asymmetrical pin positioning
- superficial infections

Based on the application and the position of the instrument, further, but rarely occurring complications can be named:

- perforation and/or fracture of the skull bone
- brain abscesses
- neurovascular damage

2.3 Safety information

2.3.1 Clinical user

General safety information

To prevent damage caused by improper setup or use and to not compromise the manufacturer warranty and liability:

- ► Use the product only according to these instructions for use.
- ► Follow the safety and maintenance instructions.
- ► Ensure that the product and its accessories are only operated and used by qualified personnel.
- ► Store any new or unused products in a dry, clean and safe place.
- ► Prior to use, check that the product is in good working order.
- ► Keep the instructions for use accessible for the user.

Note

The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

Notes on surgical procedures

It is the user's responsibility to ensure that the surgical procedure is performed correctly.

Appropriate clinical training as well as a theoretical and practical proficiency of all the required surgical techniques, including the use of this product, are prerequisites for the successful use of this product.

The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

2.3.2 Sterility

The product is supplied non-sterile and intended to be used in sterile condition.

- ► Clean the new product after removing its transport packaging and prior to its initial sterilization.

2.4 Application

The skull traction tong is used for temporary cervical traction of odontoids.

⚠ WARNING
Risk of injury and/or malfunction!
► Always carry out a function test prior to each use of the product.

The opening width of the support arms 1 can be changed by turning the spindle screw 6.

The mandrel screws 5 are screwed into the support arm 1 approximately up to the middle.

⚠ WARNING
Risk of the skull traction tong becoming loose from the skull!
► Never screw in the mandrel screw 5 all the way to the stop

The skull traction tong with its pins is attached (after an optimal small skin incision), using the spindle screw 6, directly to the temporal bone approx. 1 cm above the ears and below the equator of the skull. For tightening the wrench FF871R (SW14) can be used.

⚠ WARNING
Risk of the skull traction tong being released from the skull!
► Do not attach the skull traction tong to the head by screwing on the mandrel screw 5.
► Only tighten the skull traction tong with the spindle screw.

The tips of the mandrel screw 5 penetrate the skull bone.

The depth of penetration must be determined individually by the trained surgeon depending on the case.

⚠ WARNING
Risk of a skull fracture due to excessive tightening of the spindle screw!
► Ensure that the spindle screw is not tightened excessively.
► Take the patient's bone thickness and bone density into account.

By attaching a cord or chain to the eyelet of the tension plate 2, a tensile force can be generated in the direction of the cord or chain. To do this, the cord or chain is guided over a deflection.

While closely observing the patient's cervical spine, weights are attached to the drooping end of the cord or chain and gradually increase until the required extension is achieved.

At the same time, it must be constantly checked whether the pins are sufficiently engaging the skull bones and can take the required tensile forces. As soon as a relative movement between the skull and the pins is noticeable during the procedure, the clamping force should be carefully increased using the spindle screw 6 as assessed by the trained surgeon.

⚠ WARNING
Risk of the skull traction tong becoming loose from the skull!
► Ensure sufficient clamping force.
► Only a maximum weight of 22 kg may be attached at skull traction tong.
► The cord or chain used should be able to safely support this maximum weight.

3 Validated processing procedure

3.1 Safety information

Note

Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the processing of products.

Note

Mechanical processing should be favored over manual cleaning as it gives better and more reliable results.

Note

Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.

Note

Up-to-date information about processing and material compatibility can be found on the B. Braun eIFU site at eifu.bbraun.com

The validated steam sterilization procedure was carried out in the AESCULAP sterile container system.

3.2 General information

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore, the time interval between application and processing should not exceed 6 h; also, neither fixating precleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for processing the product. All the chemical manufacturer's application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes of materials, e.g. fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH >8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling.

- ► Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.
- ► Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to "AKI-Brochures", "Red brochure".

3.3 Service life

Materials for reusable surgical instruments are generally chosen to be suitable for repeated processing. However, it should be noted that each mechanical, chemical and thermal treatment can lead to stress and thus to aging of the material.

The service life of the product is limited by damage, normal wear, type and duration of use, as well as by handling, storage and transport of the product.

Influences of processing using the validated procedure that lead to damage to the product are not known.

Careful visual and functional inspection before each use is the best way to ensure that the product is in good functional, see Visual inspection and see Functional test.

3.4 Initial treatment and disposal at the point of use

- ► If applicable, rinse non-visible surfaces preferably with deionized water with a disposable syringe for example.
- ► Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- ► Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

3.5 Preparation before cleaning

- ▶ Remove coarse contamination by rinsing and flushing with cold, clean water.
- ▶ Disassemble products that can be disassembled, see Disassembly.

3.6 Disassembly

- ▶ Unscrew mandrel screw **5** from the screw coupling with the support arms **1**.
- ▶ Loosen flap screw **3** and unscrew it from the screw coupling with the support arms **1**.
- ▶ Remove the tension plate **2**.
- ▶ Loosen spindle screw **6** until the screw coupling separates from the joining rods **4** (right-hand and left-hand thread)

  The connection between the support arms **1** and the joining rods **4** is not loosened.

3.7 Cleaning, disinfecting and drying

3.7.1 Product-specific safety information on the processing procedure

Damage to or destruction of the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- ▶ Use cleaning and disinfecting agents according to the manufacturer's instructions.
- ▶ Observe specifications regarding concentration, temperature and exposure time.
- ▶ Do not exceed the maximum allowable disinfection temperature of 95 °C.
- ▶ If microsurgical products can be securely fixed in machines or storage devices in such a way that they will be cleaned thoroughly, clean and disinfect them mechanically.

3.7.2 Validated cleaning and disinfection procedure

Note

Processing may only take place in accordance with the following listed procedures in version V6. These are documented in the brochure "Validated Reprocessing Procedures" (AVA-V6) C63402. You will also find this brochure on the B. Braun eIFU site at eifu.bbraun.com

Validated procedure	Specific requirements	Reference
Manual cleaning with immersion disinfection	▶ Use a suitable cleaning brush. ▶ Use a disposable syringe 20 ml. ▶ Keep working ends open. ▶ Keep open and move non-rigid components. ▶ Drying phase: Use a lint-free cloth or medical compressed air.	see Manual cleaning and disinfection and subsection: ■ see Manual cleaning with immersion disinfection
Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection	▶ Use a suitable cleaning brush. ▶ Use a disposable syringe 20 ml. ▶ Place the product in a tray that is suitable for cleaning (avoiding rinsing blind spots). ▶ Keep working ends open. ▶ Connect components with lumens and channels directly to the rinsing port of the injector cart.	see Mechanical cleaning/disinfection with manual pre-cleaning and subsections: ■ see Manual pre-cleaning with a brush ■ see Mechanical alkaline cleaning and thermal disinfecting

3.8 Manual cleaning and disinfection

3.8.1 Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical/Note
I	Disinfecting cleaning	RT (cold)	> 15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ≈ 9*
II	Intermediate rinse	RT (cold)	1	–	D-W	–
III	Disinfection	RT (cold)	5	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ≈ 9*
IV	Final rinse	RT (cold)	1	–	FD-W	–
V	Drying	RT	–	–	–	–

D-W Drinking water
FD-W Fully demineralized water (low-germ, max. 10 CFU / 100 ml, as well as low endotoxin contamination, max. 0,25 endotoxin units/ml)
RT Room temperature
*Recommended B. Braun Stabimed fresh

Phase I

- ▶ Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- ▶ Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ▶ If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ▶ Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ▶ Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- ▶ Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ▶ Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ▶ Drain any remaining water fully.

Phase III

- ▶ Fully immerse the product in the disinfectant solution.
- ▶ Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- ▶ Rinse lumens at least 5 times at the beginning of the exposure time using an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

Phase IV

- ▶ Rinse/flush the product thoroughly (all accessible surfaces).
- ▶ Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- ▶ Rinse lumens with an appropriate disposable syringe at least five times.
- ▶ Drain any remaining water fully.

Phase V

- ▶ Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

3.9 Mechanical cleaning/disinfection with manual pre-cleaning

Note

The cleaning and disinfection device must be of tested and approved effectiveness (e.g. compliance with EN ISO 15883).

Note

The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

3.9.1 Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical/Note
I	Disinfecting cleaning	RT (cold)	> 15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ≈ 9*
II	Rinsing	RT (cold)	1	–	D-W	–

D-W Drinking water
RT Room temperature
*Recommended B. Braun Stabimed fresh

Phase I

- ▶ Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- ▶ Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- ▶ If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- ▶ Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- ▶ Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- ▶ Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- ▶ Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

3.9.2 Mechanical alkaline cleaning and thermal disinfecting

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Prerinse	< 25/77	3	D-W	–
II	Cleaning	55/131	10	FD-W	■ Concentrate, alkaline: – pH ≈ 13 – less than 5 % anionic surfactant ■ 0,5 % working solution – pH ≈ 11*
III	Intermediate rinse	> 10/50	> 1	FD-W	–
IV	Thermal disinfection	90/194	5	FD-W	–
V	Drying	–	–	–	According to the program for cleaning and disinfection device

D-W Drinking water
FD-W Fully demineralized water (low-germ, max. 10 CFU / 100 ml, as well as low endotoxin contamination, max. 0,25 endotoxin units/ml)
*Recommended B. Braun Helimatic Cleaner alcaline

- ▶ Check visible surfaces for residues after mechanical cleaning/disinfecting.
- ▶ Repeat the cleaning/disinfecting process if necessary.

3.10 Inspection

- ▶ Allow the product to cool down to room temperature.
- ▶ Dry the product if it is wet or damp.

3.10.1 Visual inspection

- ▶ Make sure all contaminants have been removed. Pay particular attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of teeth on rasps.
- ▶ If the product is still dirty: Repeat the cleaning and disinfection procedure.
- ▶ Inspect the product for damage, e.g., damaged insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ▶ Inspect the product for missing or faded labels.
- ▶ Check the cutting edges on the tips of the mandrel screws **5** for continuity, sharpness, notches and other damage.
- ▶ Check the surfaces for rough spots.
- ▶ Check the product for burrs that could damage tissue or surgical gloves.
- ▶ Check the product for loose or missing parts.
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.10.2 Assembly

- ▶ Connect spindle screw **6** via joint rods **4** (left and right thread) by turning and screw in until approx. 1 cm before the stop.
- ▶ Mount tension plate **2** on the collar of the flap screw **3**.
- ▶ Align the holes (threaded hole and joint hole) of the support arms **1**.
- ▶ Insert flap screw **3** with tension plate **2** into the joint hole, turn through the threaded hole and tighten as far as it will go.
- ▶ Screw the mandrel screws **5** into the support arms **1** until approximately halfway (not all the way to the stop).
- ▶ Discard non-functional products immediately and send them to Aesculap Technical Service, see 4 Technical service (4).

3.10.3 Functional test

⚠ CAUTION
Damage (metal cold welding / friction corrosion) to the product caused by insufficient lubrication!
- ▶ **Prior to function checks, lubricate moving parts (e.g., joints, pusher components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g., for steam sterilization: STERILIT I oil spray JG600 or STERILIT I drip lubricator JG598).**
- ▶ Assemble disassembled products, see Assembly.
- ▶ Check that the product functions correctly.
- ▶ Check that all moving parts are working properly (e.g. hinges, locks/latches, sliding parts etc.).
- ▶ Check whether the spindle screw **6** runs smoothly.
- ▶ Check whether the mandrel screws **5** runs smoothly but are not screwed into the holding arms until they stop (but rather approximately halfway).
- ▶ Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.11 Packaging

- ▶ Place the product in its holder or on a suitable tray, making sure it is positioned to prevent damage.
- ▶ Ensure that any fine working tips, blades and/or sharp edges are covered.
- ▶ Pack trays appropriately for the sterilization process (e.g., in AESCULAP sterile containers).
- ▶ Use sterile barrier packaging system in accordance with ISO 11607-1.
- ▶ Ensure that the packaging provides sufficient protection against contamination of the product during storage.

3.12 Steam sterilization

- ▶ Check to ensure that the sterilizing agent comes into contact with all external and internal surfaces (e.g., by opening any valves and faucets).
- ▶ Use validated sterilization process.
  - Steam sterilization using fractional vacuum process
  - Steam sterilizer according to EN 285 and validated according to ISO 17665
  - Allowed sterilization parameters, see table below
- ▶ If several devices are sterilized simultaneously in the same steam sterilizer: Make sure that the maximum allowed load according to the specifications of the manufacturer is not exceeded.

Allowed sterilization parameters

Sterilization process	T [°C]	Holding time [min]	Drying time (at least recommended) [min]
Steam sterilization (fractionated vacuum process)	134	3 - 18	20

The sterilization of products approved for 134 °C is permissible in the temperature range from 134 °C to 137 °C.

3.13 Storage

Shelf life depends on the quality of the packaging system or material, the tightness of the seals, and the storage conditions.
- ▶ Store sterile products at room temperature in a dust-free, clean, dry, and pest-free environment.
- ▶ Follow the storage instructions provided by the sterile barrier system manufacturer.

3.14 Transport

Transport and storage must not adversely affect the characteristics of the processed medical device.
- ▶ Use appropriate transport systems and aids to prevent damage or recontamination.

4 Technical service

⚠ CAUTION
Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.
- ▶ **Do not modify the product.**
- ▶ **For service and repairs, please contact your national B. Braun / AESCULAP agency.**

Service address
Aesculap Technischer Service
Am Aesculap-Platz
78532 Tuttlingen / Germany
Phone: +49 7461 95-1601
Fax: +49 7461 16-2887
E-Mail: ats@aesculap.de
Other service addresses can be obtained from the address indicated above.

5 Disposal

⚠ WARNING
Risk of infection due to contaminated products!
- ▶ **Adhere to national regulations when disposing of or recycling the product, its components and its packaging.**

⚠ WARNING
Risk of injury due to sharp-edged and/or pointed products!
- ▶ **Ensure that the packaging prevents injury by the product when disposing of or recycling the product.**

Note
The user institution is obliged to process the product before its disposal, see Validated processing procedure.
- ▶ Detailed information concerning the disposal of the product is available through the national B. Braun / AESCULAP agency, see Technical service.