

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Aesculap® Implant Systems (AIS) S4 Spinal System**  
August 6, 2013

**COMPANY:** Aesculap® Implant Systems (AIS), LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle, Sr Regulatory Affairs Specialist  
610-984-9274 (phone)  
610-791-6882 (fax)  
[lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**TRADE NAME:** AIS S4 Cervical Navigation Instruments  
**COMMON NAME:** Stereotaxic Instrument

AUG 13 2013

**REGULATION NUMBER:** 882.4560 – Instrument, Stereotaxic

**PRODUCT CODE:** OLO and HAW  
**REVIEW PANEL:** Orthopedics

**INDICATIONS FOR USE**

The AIS S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion during the navigation of pedicle screws (T1-T3).

**DEVICE DESCRIPTION**

The AIS S4 Cervical Navigation Instruments are manual surgical instruments which are designed to interface with BrainLAB's already cleared surgical navigation systems. Instruments in this system may be pre-calibrated or manually calibrated to already cleared systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general or manual functions within the orthopedic surgical environment.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The AIS S4 Cervical Navigation Instruments have similar design features, materials, and indications for use as the current AIS manual instruments (class I instrumentation)

and are substantially equivalent to the instruments used with the BrainLAB's various navigation systems. The use of the navigated polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

#### **PERFORMANCE DATA**

BrainLAB conducted validation activities including usability testing with the AIS Navigation Instruments. The AIS Navigation Instruments met the performance requirements. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the AIS Navigation Instruments.

#### **PREDICATE DEVICES**

- VectorVision Spine – K053159
- Kolibri Spine – K042721
- Trauma – K062358
- VectorVision Fluoro3D – K070106
- Spine & Trauma iCT – K083310
- BrainLab Trauma - 1100204
- Spine & Trauma 3D – K070106
- Spine & Trauma 2D / Fluoro Express – K110204
- Aesculap S4C Spinal System (K050797, K060152, K062327)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 13, 2013

Ms. Lisa M. Boyle  
Senior Regulatory Affairs Specialist  
Aesculap Implant Systems, LLC  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K130887

Trade/Device Name: Aesculap S4 Cervical Navigation Instrumentation  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: Class II  
Product Code: OLO, HAW  
Dated: June 13, 2013  
Received: June 14, 2013

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Ms. Lisa M. Boyle

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Erin D. Keith**

For

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure





K130887

March 28, 2013

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center (WO66-0609)  
 10993 New Hampshire Avenue  
 Silver Spring, MD. 20993-0002

FDA CDRH DMC  
 MAR 29 2013  
 Received

**Re: Traditional 510(k) Notification – Aesculap S4 Cervical Navigation Instrumentation**

Dear Document Control:

These documents constitute a Traditional (510(k) relating to the intent of Aesculap Implant Systems (AIS), LLC., to market S4 Cervical manual surgical instruments which are designed to interface with already cleared surgical navigation systems. The instruments are class II and should be reviewed by the Orthopedics panel. The Aesculap Navigation Instruments are indicated for use in surgical spinal procedures, but not limited to, in which the use of stereotactic surgery may be appropriate. The instruments listed in this submission have not been introduced in any other prior submissions, therefore; FDA has not provided any feedback on the subject devices.

AIS requests that FDA hold as confidential information its intent to market the Aesculap S4 Cervical Navigation Instruments as we consider this to be confidential commercial information and therefore, exempt from public disclosure, pursuant to the requirements of 21 CFR §807.95(b). An electronic copy of the application is also provided for your convenience. The eCopy is an exact duplicate of the paper copy.

In order to comply with 1920, §513 of the Safe Medical Devices Act of 1990, we have provided a 510(k) Summary of Safety and Effectiveness, as well as, a Truthful and Accurate Statement [as required by 21 CFR 807.87(j)] and the Indications for Use statement.

**Design and Use of Device:**

Question	YES	NO
Is the device intended for prescription use [21 CFR 801(d)]?	X	
Is the device intended for over-the-counter use [21 CFR 807(c)]?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X

Aesculap Implant Systems, LLC

3773 Corporate Parkway

Center Valley, PA 18034

Phone: 800-234-9179

www.aesculap.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Aesculap Implant Systems, LLC is a B. Braun company

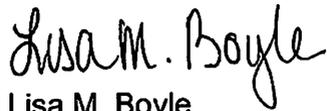
Traditional 510(k) Premarket Notification

Aesculap S4 Cervical Navigation Instrumentation

Is the device implanted?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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We trust that the information provided in the 510(k) application is sufficient for FDA to find the S4C Cervical Navigation Instruments substantially equivalent to the predicate device. If you have any questions regarding the information provided, please contact me at the number provided below. Lastly, we ask that notification of clearance be sent to Aesculap via fax at (610) 791-6882.

Sincerely,



Lisa M. Boyle  
Senior Regulatory Affairs Specialist

enclosure

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  AESCULAP IMPLANT SYSTEMS INC 3773 Corporate Parkway Center Valley PA 18034 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	2. CONTACT NAME Lisa Boyle  2.1 E-MAIL ADDRESS lisa.boyle@aesculap.com  2.2 TELEPHONE NUMBER (include Area code) 610-984-9274  2.3 FACSIMILE (FAX) NUMBER (Include Area code) 610-791-6882	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER  3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business  4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates  <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		18-Mar-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[https://userfees.fda.gov/OA\\_HTML/mdufmaCScdCfgItemsPopup.jsp?vcname=Lisa%20B...](https://userfees.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?vcname=Lisa%20B...) 3/18/2013

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Expiration Date: May 31, 2007.  
 See OMB Statement on page 5.

Date of Submission 03/28/13	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Aesculap Implant Systems, Inc.		Establishment Registration Number (if known) 3005673311	
Division Name (if applicable)		Phone Number (including area code) (610) 984-9274	
Street Address 3773 Corporate Parkway		FAX Number (including area code) (610) 791-6882	
City Center Valley	State / Province PA	ZIP/Postal Code 18034	Country USA
Contact Name Lisa M. Boyle			
Contact Title Senior Regulatory Affairs Specialist		Contact E-mail Address Lisa.boyle@aesculap.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	OLO	2	HAW	3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K070106	1	VectorVision Fluro3D / Spine & Trauma 3D	1	BrainLab
2					
3					
4					
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
Stereotaxic Instruments

	Trade or Proprietary or Model Name for This Device		Model Number
1	S4C Navigation Instruments	1	various
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission  
 Laboratory Testing       Animal Trials       Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code OLO, HAW	C.F.R. Section (if applicable) 882.4560	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedics		

Indications (from labeling)  
 The AIS S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.



Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 9610612		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Aesculap AG & Co KG			Establishment Registration Number 9610612		
Division Name (if applicable)			Phone Number (including area code) ( 011-49 ) 7461 95 2625		
Street Address Am Aesculap Platz			FAX Number (including area code) ( 011-49 ) 7461095 2177		
City Tuttlingen		State / Province	ZIP/Postal Code D-78532	Country Germany	
Contact Name Konrad Kobel		Contact Title VP of RA & QM		Contact E-mail Address konrad.kobel@aesculap.de	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 3005673311		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input checked="" type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Aesculap Implant Systems Inc..			Establishment Registration Number 3005673311		
Division Name (if applicable)			Phone Number (including area code) (610) 984-9274		
Street Address 3773 Corporate Parkway			FAX Number (including area code) ( 610 ) 791-6882		
City Center Valley		State / Province PA	ZIP/Postal Code 18034	Country USA	
Contact Name Lisa M. Boyle		Contact Title Sr. Regulatory Affairs Specialist		Contact E-mail Address Lisa.boyle@aesculap.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) (   )		
Street Address			FAX Number (including area code) (   )		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

**SECTION I****UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	5832-3	ISO	Implants for surgery – metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium, al , 1966		
2	17665-1	ISO	Sterilization of Medical Devices		
3	Standards No. 7153-1	Standards Organization ISO	Standards Title Surgical Instruments; Metallic materials; Part 1: Specifications for stainless steel	Version	Date
4	Standards No. 14971	Standards Organization ISO	Standards Title MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

**Please include any additional standards to be cited on a separate page.**

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
CDRH (HFZ-342)  
9200 Corporate Blvd.  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control*

Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(K)S**

*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 5032-3Implants for surgery -- Metallic materials -- Part 3: Wrought titanium  
6-aluminium 4-vanadium alloy. (Materials)

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-58

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard? .....         
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
 Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 17665-1:2006, Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. (Sterility)h care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA <sup>2</sup>? .....                      

FDA Recognition number <sup>3</sup> ..... # 14-261

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....                      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....                         
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....                      

Does this standard include acceptance criteria? .....                         
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard? .....                         
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....                         
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....                      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....                         
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....                         
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....                         
 If yes, was the guidance document followed in preparation of this 510k? .....                      

Title of guidance: NA

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7153-1 Surgical instruments - Metallic materials Part 1: Stainless steel 1991

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 67

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

Does this standard include acceptance criteria? .....         
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....         
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....         
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....         
If yes, report these exclusions in the summary report table.

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If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(K)**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971 Medical devices - Application of risk management to medical devices

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....         
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....      

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If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510(k)? .....      

Title of guidance: Premarket notification [510(k)] submissions for medical sterilization packaging systems in health care facilities: Draft guidance for industry and FDA, March 7, 2002

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)



March 28, 2013

U.S. Food and Drug Administration  
 Center for Devices and Radiological Health  
 Document Mail Center (WO66-0609)  
 10993 New Hampshire Avenue  
 Silver Spring, MD. 20993-0002

**Re: Traditional 510(k) Notification – Aesculap S4 Cervical Navigation Instrumentation**

Dear Document Control:

These documents constitute a Traditional (510(k) relating to the intent of Aesculap Implant Systems (AIS), LLC., to market S4 Cervical manual surgical instruments which are designed to interface with already cleared surgical navigation systems. The instruments are class II and should be reviewed by the Orthopedics panel. The Aesculap Navigation Instruments are indicated for use in surgical spinal procedures, but not limited to, in which the use of stereotactic surgery may be appropriate. The instruments listed in this submission have not been introduced in any other prior submissions, therefore; FDA has not provided any feedback on the subject devices.

AIS requests that FDA hold as confidential information its intent to market the Aesculap S4 Cervical Navigation Instruments as we consider this to be confidential commercial information and therefore, exempt from public disclosure, pursuant to the requirements of 21 CFR §807.95(b). An electronic copy of the application is also provided for your convenience. The eCopy is an exact duplicate of the paper copy.

In order to comply with ¶920, §513 of the Safe Medical Devices Act of 1990, we have provided a 510(k) Summary of Safety and Effectiveness, as well as, a Truthful and Accurate Statement [as required by 21 CFR 807.87(j)] and the Indications for Use statement.

**Design and Use of Device:**

Question	YES	NO
Is the device intended for prescription use [21 CFR 801(d)]?	X	
Is the device intended for over-the-counter use [21 CFR 807(c)]?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X

Aesculap Implant Systems, LLC

3773 Corporate Parkway

Center Valley, PA 18034

Phone: 800-234-9179

www.aesculapimplantsystems.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

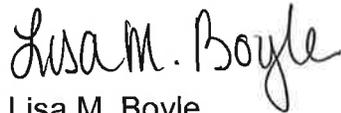
Aesculap Implant Systems, LLC - a B. Braun company

Is the device implanted?

X

We trust that the information provided in the 510(k) application is sufficient for FDA to find the S4C Cervical Navigation Instruments substantially equivalent to the predicate device. If you have any questions regarding the information provided, please contact me at the number provided below. Lastly, we ask that notification of clearance be sent to Aesculap via fax at (610) 791-6882.

Sincerely,



Lisa M. Boyle  
Senior Regulatory Affairs Specialist

enclosure

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**SECTION I  
REQUIRED STATEMENTS**

**INDICATIONS FOR USE STATEMENT  
510(k) SUMMARY  
TRUTHFUL AND ACCURATE STATEMENT  
CLASS III SUMMARY AND CERTIFICATION  
FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT  
DECLARATION OF CONFORMITY**

Page 1 of 1

**A. INDICATIONS FOR USE STATEMENT**

**510(k) Number:** \_\_\_\_\_

**Device Name: Aesculap S4 Cervical Navigation Instrumentation**

**Indications for Use:**

The Aesculap S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

Prescription Use     X     and/or Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

\_\_\_\_\_  
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Aesculap® Implant Systems (AIS) S4 Spinal System**  
March 28, 2013

**COMPANY:** Aesculap® Implant Systems (AIS), LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle, Sr Regulatory Affairs Specialist  
610-984-9274 (phone)  
610-791-6882 (fax)  
[lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**TRADE NAME:** AIS S4 Cervical Navigation Instruments  
**COMMON NAME:** Stereotaxic Instrument

**REGULATION NUMBER:** 882.4560 – Instrument, Stereotaxic

**PRODUCT CODE:** OLO and HAW  
**REVIEW PANEL:** Orthopedics

**INDICATIONS FOR USE**

The AIS S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

**DEVICE DESCRIPTION**

The AIS S4 Cervical Navigation Instruments are manual surgical instruments which are designed to interface with BrainLAB's already cleared surgical navigation systems. Instruments in this system may be pre-calibrated or manually calibrated to already cleared systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general or manual functions within the orthopedic surgical environment.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The AIS S4 Cervical Navigation Instruments have similar design features, materials, and indications for use as the current AIS manual instruments (class I instrumentation) and are substantially equivalent to the instruments used with the BrainLAB's various navigation systems.

**PERFORMANCE DATA**

BrainLAB conducted validation activities including usability testing with the AIS Navigation Instruments. The AIS Navigation Instruments met the performance requirements. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the AIS Navigation Instruments.

**PREDICATE DEVICES**

- K070106 – BrainLAB VectorVision Fluro3D / Spine & Trauma 3D

**C. PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT**  
[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Regulatory Affairs Specialist for Aesculap<sup>®</sup> Implant Systems LLC., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

*Dina M. Boyle*  
Senior Regulatory Affairs Specialist

03/28/13  
Date

\_\_\_\_\_  
Premarket Notification 510(k) Number

**D. CLASS III SUMMARY AND CERTIFICATION**

This section does not apply.

**E. FINANCIAL CERTIFICATION AND DISCLOSURE STATEMENT**

This section does not apply.

**F. DECLARATION OF CONFORMITY AND SUMMARY REPORTS**

This section does not apply.

**SECTION II  
GENERAL INFORMATION**

**DEVICE NAME  
DEVICE SPONSOR  
REGULATORY CLASSIFICATION  
PURPOSE FOR PREMARKET NOTIFICATION  
DEVICE DESCRIPTION  
INDICATIONS FOR USE  
SUBSTANTIAL EQUIVALENCE  
PERFORMANCE STANDARDS  
QUALITY CONTROL  
FUNDAMENTAL SCIENTIFIC TECHNOLOGY  
MANUFACTURING FACILITY**

**II. GENERAL INFORMATION****A. DEVICE NAME**

1. Trade Name: AIS S4 Cervical Navigation Instruments
2. Common Name: Stereotaxic Instrument

**B. DEVICE SPONSOR**

1. Est. Registration No: 3005673311
2. Name / Address: Aesculap® Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034
3. Contact Person: Lisa M. Boyle  
Senior Regulatory Affairs Specialist  
800-258-1946 x 5274  
610-791-6882 (fax)  
[lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**C. REGULATORY CLASSIFICATION**

1. Device Class: Class II
2. Product Code: HAW and OLO
3. Classification Number: 884.4560
4. Classification Name: Neurological / Orthopedic Stereotaxic Instrument
5. Review Panel: Orthopedic

**D. PURPOSE FOR PREMARKET NOTIFICATION**

The S4 Cervical Navigation Instruments described in this submission represents the introduction of Aesculap Instrumentation for use with the BrainLab already cleared navigation systems.

**E. DEVICE DESCRIPTION**

The AIS S4 Cervical Navigation Instruments are manual surgical instruments which are designed to interface with BrainLAB's already cleared surgical navigation systems. Instruments in this system may be pre-calibrated or manually calibrated to already cleared systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general or manual functions within the orthopedic surgical environment.

**F. INDICATIONS FOR USE**

The AIS S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

**G. SUBSTANTIAL EQUIVALENCE**

The AIS Navigation Instruments have been verified and validated according to BrainLAB's procedures for product design and development. The validation proves substantial equivalence as well as the safety and effectiveness of the system.

**H. PERFORMANCE STANDARDS**

BrainLAB conducted validation activities including usability testing with the AIS Navigation Instruments. The AIS Navigation Instruments met the performance requirements. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the AIS Navigation Instruments.

The results of the testing showed that the subject devices meet or exceed the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

**I. QUALITY CONTROL**

The S4 Cervical Navigation Instruments are manufactured by Aesculap AG, and distributed by Aesculap Implant Systems, Inc. These devices are manufactured and processed to applicable standards. Quality control checks are done on all finished products to ensure that product specifications are met before the product is released.

**J. MANUFACTURING FACILITY (INSTRUMENTS)**

1. Manufacturing Facility:

Aesculap AG  
Am Aesculap-Platz  
Tuttlingen Germany  
Tel: +497461952625  
Fax: +497461952969  
Konrad Kobel  
Vice President, Regulatory & Quality Management

**SECTION III  
DEVICE DESCRIPTION**

**BACKGROUND  
INSTRUMENTATION  
DRAWINGS**

**III. DEVICE DESCRIPTION**

**A. BACKGROUND – BrainLab’s Navigation Systems**

BrainLab’s Navigation Systems are used as an intra-operative image-guided localization system to enable minimally invasive surgery. BrainLab’s System links a freehand probe, tracked by a passive maker sensor system to virtual computer image space on a patient’s preoperative or intra-operative 2D or 3D image data.

BrainLab’s spine software application enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intra-operatively by an appropriate image acquisition system. The software offers screw implant size planning and navigation on rigid bone structures with pre-calibrated and additional individually – calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic mage reconstruction) and /or an image data based model of the anatomy.

BrainLab has several navigation system 510(k)’s that have been cleared by FDA with the use of pre-calibrated / manual-calibrated instrument use for spinal applications: K042721 – BrainLAB Kolibri Spine, K053159 – BrainLAB Vector Vision Spine , K062358 – BrainLAB Trauma, K070106 – BrainLAB VectorVision Fluro3D / Spine & Trauma 3D, K083310 – BrainLAB Spine & Trauma ICT, and K110201 – BrainLAB Trauma / Spine & Trauma 2D / Fluoro Express.

BrainLab’s Instrument Star units cleared in BrainLab’s Trauma System (K070106) will work in conjunction with the Aesculap instruments listed below. BrainLab had provided Aesculap with a reference letter. This letter can be found in Appendix A. Verification testing has also been completed by BrainLab and can be found in the Performance Section of this submission.

55830-20A	Instrument Star Unit (Pre-calibrated) (K070106)	
55830-25A	INSTRUMENT STAR UNIT ML (CALIBR.W/ICM4) (K070106)	

**B. Aesculap Instrumentation**

The Aesculap Instruments listed below will be integrated with BrainLab's Navigation Systems.

Part#	Description	Picture
FW652R	Aesculap Star Unit Navigation Attachment	
FW 653R	Cortical Punch for Navigated Drill Guide FW654R	
FW654R	Navigated Drill Guide D3.5mm, Short	
FW655R	Navigated Screw Tap, D3.5mm	
FW656R	Navigated Screw Driver for Polyaxial Screws	
FW657R	Reducing Sleeve D13mm for Calibration Tool	
FW658R	Navigation Guide Sleeve D4.0mm – Smooth Shank	

FW660R	Navigated Guide Sleeve D3.5 / 4.0mm	
FJ985R	C1/C2 Inner Sleeve Guide D4.0mm	
FW661R	C1/C2 Inner Sleeve Guide D3.5mm	
FW662SU	C1/C2 Drill Bit D2.4mm	
FW663R	C1/C2 Screw Tap 3.5mm	

**C. DRAWING**

The drawing for the Aesculap Navigation Instruments can be found on the next page.

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

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Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

**SECTION IV  
SUBSTANTIAL EQUIVALENCE**

**COMPARATIVE TABLE  
PREDICATE DEVICE INFORMATION**

**IV. SUBSTANTIAL EQUIVALENCE**  
**A. COMPARATIVE TABLE**

The device comparison information that is found on the following pages has been completed by BrainLab- manufacturer of the Navigation System (K070106).

# EXPERIENCES FROM PREVIOUS PRODUCTS

FORM 04-203 :: REVISION 02

RELEASED February 13, 2013



## 1 INTRODUCTION

The purpose of this document is to compare the new medical device with a device previously cleared by the FDA, cleared device.

It documents the similarities as well as differences regarding safety and effectiveness of the new medical device compared to the previous device, including a comparison of the indications for use.

## 2 COMPARATIVE INFORMATION ON PREDICATE DEVICE

Item	Information
Predicate Device	<ul style="list-style-type: none"> <li>Brainlab pre-calibrated and/or manual-calibrated spine instruments (Awl, Probe and Star Units)</li> <li>Brainlab pre-calibrated Drill Guide (e.g. for use with Ulrich neon cervical system)</li> </ul> <p>integrated into following Brainlab systems:</p>
510 (k)	<p>K053159 VectorVison Spine (Version 5.5 and 5.6)</p> <p>K042721 Kolibri Spine (Version 2.0)</p> <p>K062358 Trauma (Version 2.6)</p> <p>K070106 VectorVision Fluoro3D (Version 1.6 and 2.0)</p> <p>Spine &amp; Trauma 3D (Version 2.0)</p> <p>K083310 Spine&amp;Trauma iCT (Version 1.0)</p> <p>K110204 Brainlab Trauma (Version 3.0)</p> <p>Spine &amp; Trauma 2D / Fluoro Express (Version 3.1)</p>
New Device	Aesculap Spine pre-calibrated and/or manual-calibrated (= calibration with ICM4) spine instruments for S <sup>4</sup> Cervical
Responsibilities	<p><b>Brainlab</b></p> <ul style="list-style-type: none"> <li>- Predicate Device</li> <li>- Software Integration of New Device into Predicate Device</li> </ul> <p><b>Aesculap</b></p> <ul style="list-style-type: none"> <li>- Instrument design and manufacturing of New Device</li> </ul>

Note:

The following table compares only the relevant aspects for integration and navigation of Aesculap S<sup>4</sup> Cervical instruments (= New Device) into existing Brainlab software applications (= Predicate Device).

# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Indications for use</b></p>	<p>Brainlab spine application is intended as an intra-operative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient’s preoperative or intra-operative 2D or 3D image data.</p> <p>Spine software application enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intra-operatively by an appropriate image acquisition system.</p> <p>The software offers screw implant size planning and navigation on rigid bone structures with pre-calibrated and additional individually-calibrated surgical tools.</p> <p>The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.</p>	<p>“Indications for use” concerning navigational use for spinal applications of New Device are covered by and same as Brainlab Predicate Device.</p> <p>Further “indications for use” are covered by Aesculap Predicate Device (= non-navigated S<sup>4</sup> Cervical instruments).</p>	<p>Applicable for pre-calibrated and manual-calibrated instruments.</p> <p><u>Note:</u> As “Indications for use” of Brainlab Predicate Device only “Indications for use” of VV Fluoro 3D 2.0 (K070106) are shown and shall be used as predicate device reference.</p> <p>“Indications for use” of other Brainlab Predicate Devices concerning pre-calibrated / manual-calibrated instrument use for spinal applications are comparable to each other.</p>

## EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap Integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Description</b></p> <p><b>Pre-calibrated Instruments</b></p>	<p>Pre-calibrated instruments integrated into the Brainlab spine software application are required to perform surgical procedures under navigational control as defined within indications for use.</p> <p>The dimensions and 3D shape of each instrument is stored in the system by individual files.</p> <p>Any pre-calibrated instrument can be selected in software, is tracked by passive marker sensor system, and is displayed with its real 3D shape relatively to virtual computer image based on registered patient anatomy / bone model.</p> <p>After successful verification / validation testing demonstrating safe and effective use / integration, new pre-calibrated instruments can simply be added to and used with existing software applications by installing corresponding pre-calibrated tool files to corresponding system folder.</p> <p>No software change is required.</p>	<p>Special instruments are available from Aesculap for use with corresponding Aesculap S<sup>4</sup> Cervical spinal implant system (e.g. pedicle preparation for screw placement). Once those instruments are integrated into Brainlab navigation system as pre-calibrated instrument, their real 3D shape is displayed on the navigation screen and instrumentation procedure can be performed with support of navigational control.</p> <p>Integrated rotationary instrument - tap - has dedicated and specified interface for receiving compatible Brainlab Star Unit and overall tolerances are adapted / tightened to enable accurate pre-calibrated use for the intended clinical application.</p> <p>Integrated guide instruments - drill guide / guide sleeves - have dedicated and specified interface for receiving Aesculap IGS Star Unit “pre-calibrated” and overall tolerances are adapted / tightened to enable accurate pre-calibrated use for the intended clinical application. The Aesculap IGS Star Unit “pre-calibrated” has same star geometry as Brainlab Drill Guide handle (Art.Nr. 41839) or IGS Star Unit “pre-calibrated” (Art.Nr. 55830-20A) as well as same pins for receiving Brainlab reflective marker spheres.</p> <p>Integrated pre-calibrated instruments are listed in chapter 3.2.</p>	<p>Applicable for pre-calibrated instruments.</p> <p>Intended use of integrated instruments as well as invasive part and geometrical shapes that are relevant for safe and effective implant placement are not changed and are same as used for standard non-navigated instrument.</p> <p>Only difference is that the pre-calibrated instruments have a dedicated interface for IGS tracking array attachment and their tolerances / accuracies are more enhanced.</p>

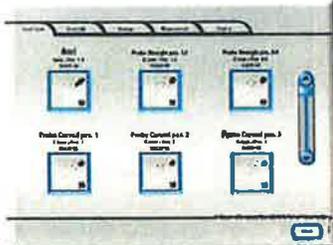
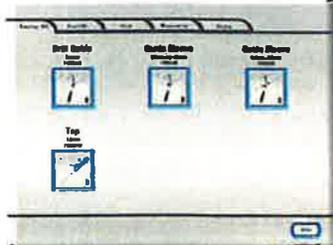
# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap Integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Software Integration</b></p>	<p>BLPCT File Format PCI File Format</p>	<p>Same as predicate device</p>	<p>Applicable for pre-calibrated instruments.</p> <p>= software format and framework that defines and describes pre-calibrated integration of instruments into compatible / supported Brainlab navigation software.</p> <p>Same performance and technology used for new device.</p>
<p><b>Instrument selection</b></p>	<p>“BrainLAB” tab in software displaying selection button for each integrated instrument.</p> 	<p>Display and selection of integrated instruments is the same.</p> <p>Own tab for integrated system: <b>Aesculap_S4C</b></p> 	<p>Applicable for pre-calibrated instruments.</p> <p>Same performance and technology used for new device.</p>
<p><b>Accuracy</b></p>	<p>~1 – 2 mm for Awl, Probe, Drill Guide</p> <p>(Stored accuracy threshold for pre-calibrated validation = 2mm)</p>	<p>Same as predicate device ~1 – 2 mm for Tap, Drill Guide, Guide Sleeves</p> <p>(Stored accuracy threshold for pre-calibrated validation = 2mm)</p>	<p>Applicable for pre-calibrated instruments.</p> <p>Same performance and technology used for new device.</p> <p>Tolerances of new pre-calibrated instrument are defined and calculated accordingly to fulfill same accuracy threshold for validation.</p>

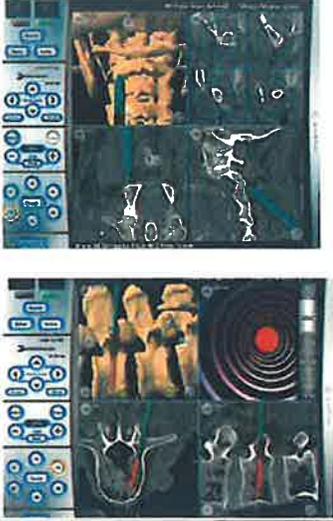
# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Representation</b></p>	<p>Real 3D shape of instrument is displayed in software on navigation screen.</p> 	<p>Same as with predicate device</p> 	<p>Applicable for pre-calibrated instruments.</p> <p>Same performance and technology used for new device.</p>

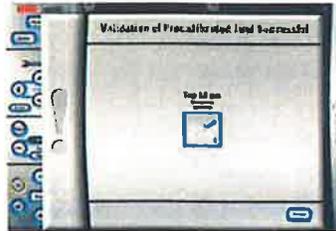
**EXPERIENCES FROM PREVIOUS PRODUCTS**

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Verification / Validation</b></p>	<p><b>Verification</b> enables user in Software to visually check instrument tip accuracy at known areas of Brainlab ICM4 (= Instrument Calibration Matrix Rev.4) Art.Nr. 41874.</p>  <p><b>Validation</b> enables user to get accuracy automatically checked by system using Brainlab ICM4 (= Instrument Calibration Matrix Rev.4) Art.Nr. 41874. Navigation system calculates instrument tip accuracy and compares value with set accuracy threshold. If accuracy threshold is exceeded, use is denied.</p>  	<p>Same as predicate device</p>   	<p>Applicable for pre-calibrated instruments.</p> <p>Same performance and technology used for new device.</p> <p>For verification / validation of Guide Sleeve C1 (FW658R) special calibration insert (FW657R) for 30mm receptacle of ICM4 is available that is comparable to and has same tolerances as Brainlab calibration insert (Art.Nr. 41839-99) used for verification / validation of predicate device (Brainlab Drill Guide Trocars Art.Nr. 41839-90 / 41839-95).</p>

# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Description</b></p> <p><b>Manual-calibrated instruments</b></p>	<p>For manual-calibrated instruments dedicated Star Units are used that have unique but different marker geometry as in comparison to pre-calibrated use. A manual-calibrated instrument must be calibrated each time before use using Brainlab ICM4 (calibration device) Art.Nr. 41874.</p> <p>After successfully calibration of instrument's axis and tip its accuracy can be directly verified on the navigation screen and can be used to perform surgical procedures under navigational control as defined within indications for use.</p> <p>The calibrated instruments are displayed in generic shapes (e.g. simple cylinder or generic screw).</p>  <p>Software integration tests or installations are not mandatory and not required prior to use.</p>	<p>Special instruments are available from Aesculap for use with Aesculap S<sup>4</sup> Cervical spinal implant system (i.e. rotary screwdriver for pedicle screw insertion).</p> <p>Once those instruments are calibrated manually, they are displayed as generic shape on the navigation screen and instrumentation procedure can be performed with support of navigational control.</p> <p>Integrated manual-calibrated instruments are listed in chapter 3.2.</p>	<p>Applicable for manual-calibrated instruments.</p> <p>Intended use of manual-calibrated instruments as well as invasive part and geometrical shapes that are relevant for safe and effective implant placement are not changed and are same as standard non-navigated instrument.</p> <p>Same performance and technology used for new device.</p>

# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device – Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<b>Accuracy</b>	(~1 – 2 mm)  Achieved / calculated calibration accuracy is displayed after calibration and can be verified.	Same as predicate device	Applicable for manual-calibrate instruments.  Depending on system accuracy and outcome of manual-calibration.  Same performance and technology used for new device.
<b>Localization technique</b>	Based on infrared light.  The infrared light is emitted by IR LEDs located in the cameras of the IGS system. This light is reflected by the highly reflecting markers mounted directly on the Star Unit. The camera receives the reflected light for detection of 3D position of instrument.	Same as predicate device	Applicable for pre-calibrated and manual-calibrated instruments.  Same performance and technology used for new device.
<b>Interface</b>	Awl, Probe instrument have interface for Brainlab IGS Star Unit “pre-calibrated” (Art.Nr. 55830-20A) and/or IGS Star Unit “Calibration with ICM4” (Art.Nr. 55830-25A / -29)  For Drill Guide “pre-calibrated” marker geometry is incorporated into handle that can receive various interchangeable guide tubes.	For rotationary instruments - tap and screwdriver - same as predicate device Brainlab Awl and Probe.  For guide instruments - Drill Guide and Guide Sleeves - same “pre-calibrated” star geometry is incorporated into Aesculap IGS Star Unit design and interface to Brainlab system is shifted to the pins for receiving Brainlab reflective marker spheres.	Applicable for pre-calibrated and manual-calibrated instruments.  New devices use same Brainlab IGS Star Unit “pre-calibrated” (Art.Nr. 55830-20A) and IGS Star Unit “Calibration with ICM4” (Art.Nr. 55830-25A / -29) or have same geometries incorporated into Aesculap IGS Star Unit design.

# EXPERIENCES FROM PREVIOUS PRODUCTS

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Applicable for Brainlab and Aesculap	Predicate Device - Brainlab (software – instrument navigation)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<p><b>Components</b></p>	<p>Brainlab Spine Instruments:</p> <ul style="list-style-type: none"> <li>• Instrument tip</li> <li>• Star Unit</li> <li>• Handle</li> </ul>  <p>For <b>pre-calibrated</b> use: IGS Star Unit Star Unit “Pre-calibrated” (Art.Nr. 55830-20A, -27)</p>  <p>For <b>manual-calibrated</b> use: IGS Star Unit “Calibration with ICM4” (Art.Nr. 55830-25 / -29)</p>  <p>Brainlab Drill Guide – for pre-calibrated use only:</p> <ul style="list-style-type: none"> <li>• Handle with star</li> <li>• Guide Tube</li> <li>• Drill</li> </ul> 	<p><u>S<sup>4</sup>C Tap and Screwdriver:</u></p> <ul style="list-style-type: none"> <li>• Instrument tip (→ Aesculap)</li> <li>• Star Unit (→ Brainlab)</li> <li>• Marker Spheres (→ Brainlab)</li> <li>• Handle (→ Aesculap)</li> </ul>  <p><u>S<sup>4</sup>C Drill Guide and Guide Sleeves:</u></p> <ul style="list-style-type: none"> <li>• Guide instrument (→ Aesculap)</li> <li>• Star Unit (→ Aesculap)</li> <li>• Marker Spheres (→ Brainlab)</li> </ul>  <p>Integrated manual-calibrated instruments are listed in chapter 3.2.</p>	<p>Applicable for <b>pre-calibrated</b> and <b>manual-calibrated</b> instruments.</p> <p>New S4C instruments – tap and screwdriver - use same Brainlab Star Units as predicate devices for <b>pre-calibrated</b> and / or <b>manual-calibrated</b> use.</p> <p>New S4C Drill Guide and Guide Sleeves use Aesculap IGS Star Unit having same Brainlab star geometry with pins for reflective marker spheres as predicate Brainlab Drill Guide for <b>pre-calibrated</b> use.</p>

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Applicable for Aesculap	Predicate Device – Brainlab (Brainlab standard IGS instruments and Star Units)	New Device - Aesculap integrated spine instruments for S <sup>4</sup> Cervical	Comment
<b>Patient contact</b>	Invasive, mainly with instrument tip.	Same as predicate device	Applicable for pre-calibrated and manual-calibrated instruments.
<b>Labeling</b>	Brainlab logo Serial-number CE0123 sign	Aesculap logo Part Number Lot- / Serial-number CE0123 sign "only to be used with Brainlab"	Applicable for pre-calibrated and manual-calibrated instruments.  Product labeling refers here to instruments only.  No labeling change on Brainlab system and Brainlab Star Units required.
<b>Materials</b>	Biocompatible materials: - medical stainless steels - medical grade plastics (PEEK) or silicone	Same as predicate device In addition - titanium	Applicable for pre-calibrated and manual-calibrated instruments.  All parts getting in contact with patient comply with ISO 10993-1 or corresponding material standards.
<b>Sterility Reprocessing</b>	Delivered non-sterile Re-usable Steam sterilization	Same as predicate device	Applicable for pre-calibrated and manual-calibrated instruments.

## 3 APPENDIX

### 3.1 BRAINLAB DRAWINGS OF PREDICATE DEVICE

#### Assembly Drawings

55830-xx Spine Instrument Set – Pre-calibrated  
41839-xx Drill Guide Kit – for use with Ulrich neon

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### 3.2 LIST OF INTEGRATED AESCULAP SPINE INSTRUMENTS

**Pre-calibrated instruments** for use with **Brainlab IGS Tool Star Unit "Pre-calibrated" (55830-20A):**

Aesculap Product Code	Description
<b>FW655R</b>	<b>S<sup>4</sup>C Tap 3.5mm</b>
<u>Compatible accessories for FW655R:</u>	
FW165R	Softgrip Handle with ratchet
FW067R	Softgrip Handle without ratchet

**Pre-calibrated instruments** for use with **Aesculap IGS Star Unit Pre-calibrated (FW652R):**

Aesculap Product Code	Description
<b>FW654R</b>	<b>S<sup>4</sup>C Drill Guide 3.5mm</b>
<b>FW658R</b>	<b>S<sup>4</sup>C Guide Sleeve C1 for "smooth shank" screws</b>
<b>FW660R</b>	<b>S<sup>4</sup>C Guide Sleeve C1/C2 4.0mm / 3.5mm</b>
<u>Compatible accessories for FW654R:</u>	
FW653R	S <sup>4</sup> C Awl
FW051SU	S <sup>4</sup> C Drill Bit 2.4mm
<u>Compatible accessories for FW658R:</u>	
FW657R	S <sup>4</sup> C Calibration Insert
FW085R	S <sup>4</sup> C Smooth Shank Bone Awl
FW086SU	S <sup>4</sup> C Smooth Shank Screw Drill
FW087R	S <sup>4</sup> C Smooth Shank Screw Tap
<u>Compatible accessories for FW660R:</u>	
FW661R	S <sup>4</sup> C C1/C2 Inner Drill Guide 3.5mm
FW662SU	S <sup>4</sup> C C1/C2 Drill Bit 2.4mm, for use with FW661R
FJ985R	S <sup>4</sup> C C1/C2 Inner Drill Guide 4.0mm
FW088SU	S <sup>4</sup> C C1/C2 Drill Bit 2.9mm, for use with FJ985R
FW663R	S <sup>4</sup> C C1/C2 Tap 3.5mm
FW089R	S <sup>4</sup> C C1/C2 Tap 4.0mm
FW069R	S <sup>4</sup> C C1/C2 Screwdriver
FJ983R	S <sup>4</sup> C Apfelbaum C1/C2 Obturator
FJ984R	S <sup>4</sup> C Apfelbaum C1/C2 Trocar

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**Manual-calibrated instruments** for use with **Brainlab IGS Tool Star Unit "Calibration with ICM4"** (55830-25A):

Aesculap Product Code	Description
<b>FW656R</b>	<b>S<sup>4</sup>C Screwdriver</b>

Compatible accessories for FW656R:

FW165R	Softgrip Handle with ratchet
FW067R	Softgrip Handle without ratchet

## 4 APPROVALS

I confirm that the contents of this document are correct.

Project Manager

Feb 19 2013 15:22:23 +01:00

X  ✓

Christian Lechner

I am approving this document

CDR Review Group

Feb 22, 2013

X 

CDR Review Group

K. SCHWIBSCH  
has approved this document









**B. Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]**

New Device [Aesculap<sup>®</sup> Implant Systems<sup>®</sup> S4 Cervical Navigation Instruments] are Compared to the Marketed Device(s) [BrainLab VectorVision Fluoro3D and Spine/Trauma 3D System (K070106)] .

**Does New Device Have Same Indication Statements?**

**Yes.** The indications for the new cervical navigation instruments are the same as the predicate device instruments used in navigation.

**New Device Has Same Intended Use and May be "Substantially Equivalent".**

**Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

Design (compared to BrainLab Instrumentation): **Yes.** The S4C navigation instruments are similar in design to the BrainLab instruments. Both the new and predicate systems have similar instruments/tips, star units, and instrument handles. The instruments are integrated into the BrainLab navigation system. Once integrated as either a pre-calibrated or manual calibrated, they are displayed as a 3D or generic shape on the screen. The instrument procedure can then be performed with support of the navigational control.

The Aesculap S4C Navigation Instruments have been validated to work in conjunction with the BrainLab Navigation System. BrainLab has performed the validation testing. The results demonstrated that the S4C Navigation Instruments are safe and effective and substantially equivalent to the predicate.

Material: **Yes.** The materials of the S4C Navigation Instruments (medical grade stainless steel, titanium, PEEK, and silicone) are the same materials used in the manufacturing of the predicate devices.

**Could the New Characteristics Affect Safety or Effectiveness? No.**

Overall, the S4C Navigation Instruments do not impart any new technological characteristics or features from the competitive devices. When compared to the predicate devices, the subject device demonstrates substantial equivalency in terms of design, performance characteristics and indications for use. BrainLab has completed the validation testing for the S4C Navigation Instrument. It can be found in Section IX.

**Substantial Equivalence Determination.**

**SECTION V  
LABELING INFORMATION**

**PACKAGE LABEL  
PACKAGE INSERT**

**V. LABELING INFORMATION**  
**A. PACKAGE LABELS**

The Aesculap S4 Navigation Instruments are marked with the company name, catalog number, product description, device material, lot number, length and/or size.

The following are examples of the package labels that are on the outside of the pouch.

**Sample Label for Non-Sterile Product:**



Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

**B. PACKAGING INSERT FOR INSTRUMENTS**

A copy of the package insert is located on the following pages. The packaging insert has been developed by Germany.

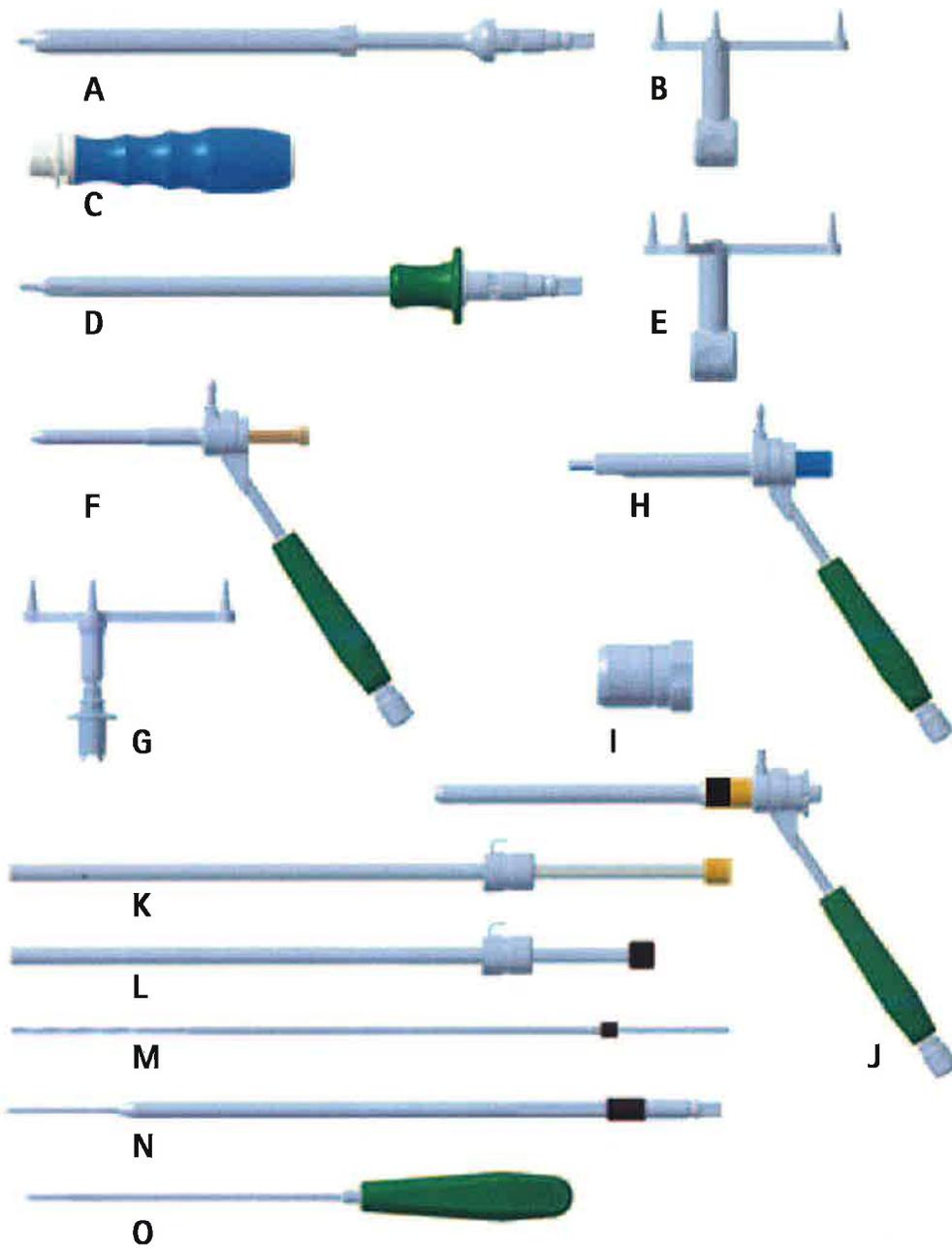
# Aesculap Spine

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- GB** Instructions for use/Technical description
- USA** S<sup>4</sup> Cervical - Navigated Instruments
- D** Gebrauchsanweisung/Technische Beschreibung  
S<sup>4</sup> Cervical - Navigierte Instrumente
- F** Mode d'emploi/Description technique  
S<sup>4</sup> Cervical - Instruments navigués
- E** Instrucciones de manejo/Descripción técnica  
S<sup>4</sup> Cervical Instrumental de navegación
- I** Istruzioni per l'uso/Descrizione tecnica  
S<sup>4</sup> Cervical - Strumenti navigati
- P** Instruções de utilização/Descrição técnica  
S<sup>4</sup> Cervical - Instrumentos de navegação
- NL** Gebruiksaanwijzing/Technische beschrijving  
S<sup>4</sup> Cervical - genavigeerde instrumenten
- DK** Brugsanvisning/Teknisk Beskrivelse  
S<sup>4</sup> Cervical - Navigerede instrumenter
- CZ** Návod k použití/Technický popis  
Navigované nástroje S<sup>4</sup> Cervical

**B | BRAUN**  
SHARING EXPERTISE





## Safe handling and preparation

### CAUTION

Federal law restricts this device to sale by or on order of a physician!



WARNING

**Risk of injury caused by incorrect operation of the product!**

- Attend appropriate product training before using the product.
- For information regarding such training, please contact your national B. Braun/Aesculap agency.

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, follow, and keep safe the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Remove the transport packaging and thoroughly clean the new product, either manually or mechanically, prior to its initial sterilization.
- Store any new or unused products in a dry, clean, and safe place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts.
- To avoid damage to the working end: Carefully insert the product through the working channel (e.g. trocar).

Ø S<sup>4</sup>C1/C2 drill bit 2.4 mm (FW662SU), standard drill Ø 2.4 mm (FW051SU), Favored Angle screw drill Ø 2.9 mm (FW088SU) and drill Ø 2.9 mm for smooth-shank screws (FW086SU)



DANGER

**Risk of infection of patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!**

- Do not reuse the product.

The product is gamma-sterilized and ships in sterile packaging.

The product must not be reused.

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, follow, and keep safe the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Do not use products from open or damaged sterile packaging.

- Prior to each use, inspect the product for loose, bent, broken, cracked or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Do not use the product after expiry of its use-by date.

## Safe operation



WARNING

**Risk of injury and/or malfunction!**

- Always carry out a function check prior to using the product.



WARNING

**Risk of injury to the patient!**

- Handle S<sup>4</sup>C instruments with the greatest of care as they are extremely precise and highly sensitive.
- Check accurate calibration of dropped or damaged S<sup>4</sup>C instruments, or send them to the Aesculap Technical Service.



WARNING

**Risk of injury to the patient!**

- Prior to the operation, plan the configuration of the operating room, the assembly of the instruments and the alignment of the reference star.
- Ensure that the navigation camera has an unrestricted view on the reflective marker spheres of the instruments.



WARNING

**Risk of injury to the patient!**

- Ensure that the instruments used are not bent or damaged.
- Before use, check the precision of the instruments, particularly that of fine instruments. For this, hold the instrument tip in the pivot point of the Brainlab Instrument Calibration Matrix Rev. 4.



WARNING

**Risk of injury to the patient!**

- Use navigated S<sup>4</sup>C instruments only with Brainlab disposable reflective marker spheres.

### Note

For further information on the correct handling of the marker spheres, see corresponding Brainlab user manual.

## S<sup>4</sup> Cervical - Navigated Instruments

### Legend

- A Navigated screw tap Ø 3.5 mm (FW655R)
- B IGS Tool Star Unit (pre-calibrated) (Brainlab) (55830-20A)
- C Handle (FW165R with ratchet or FW067R without ratchet)
- D Navigated screwdriver for polyaxial screw (FW656R)
- E IGS Tool Star Unit ML (calibration with ICM4) (Brainlab) (55830-25A)
- F Navigated drill guide Ø 3.5 mm, short (FW654R)
- G Aesculap star unit Navigation attachment (FW652R)
- H Navigated guide sleeve Ø 4.0 mm for smooth-shank screws (FW658R)
- I Reduction sleeve Ø 13 mm for Brainlab Instrument Calibration Matrix Rev. 4 (FW657R)
- J Navigated guide sleeve Ø 3.5/4.0 mm (FW660R)
- K C1/C2 inner sleeve guide Ø 4 mm (FJ985R)
- L C1/C2 inner sleeve guide Ø 3.5 mm (FW661R)
- M C1/C2 drill bit Ø 2.4 mm (FW662SU)
- N C1/C2 screw tap Ø 3.5 mm (FW663R)
- O Cortical punch for navigated drill guide FW654R (FW653R)

### Symbols on product and packages

Symbol	Explanation
	Sterilization using irradiation
	Not for reuse in intended applications as defined by the manufacturer
	Use by
	Caution, general warning symbol Caution, see documentation supplied with the product
	Date of manufacture

### Intended use

The S<sup>4</sup> Cervical System (S<sup>4</sup>C System) is used for posterior cervical and thoracic stabilisation and fusion. Indications and contraindications are specified in the instructions for use for implants (TA011796). The instruments listed in the captions form part of this system. They are used for the individual adaptation, positioning and insertion of S<sup>4</sup>C implants in patients. For safe usage, follow instructions for use for S<sup>4</sup>C System Instruments (TA011984) and Operating Technique (O34202).

The instruments listed in the captions may only be used with the Brainlab navigation system. For safe handling prior to the operation, read Spine & Trauma user manual for Brainlab instruments and the corresponding software manual for the Brainlab spine application used.

### Combination specifications

Aesculap and Brainlab accept absolutely no responsibility if instruments, awls or drills other than those named below are used with the corresponding drill guides and guide sleeves.

- Only combine S<sup>4</sup>C navigated drill guide **F** with:
  - S<sup>4</sup>C-cortical punch for S<sup>4</sup>C-drill guide **O**
  - Standard drill bit, Ø 2.4 mm for Ø 3.5 mm screws (FW051SU)
- Only combine S<sup>4</sup>C navigated guide sleeve Ø 4.0 mm **H** for smooth-shank screws with:
  - Smooth-shank screw bone awl (FW085R)
  - Smooth-shank screw drill (FW086SU)
  - Smooth-shank screw tap (FW087R)
  - Polyaxial screwdriver (FW070R)
  - Navigated screwdriver for polyaxial screw (FW656R)
  - Apfelbaum ball end screwdriver, short (FJ968R)
- Only combine S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm **J** with:
  - approved Apfelbaum C1/C2 obturator (FJ983R)
  - Apfelbaum trocar (FJ984R)
  - Favored Angle screw drill Ø 2.9 mm for Ø 4 mm screws (FW088SU)
  - Favored Angle screw tap Ø 4 mm (FW089R)
  - C1/C2 inner sleeve guide Ø 4 mm **K** (FJ985R)
  - S<sup>4</sup>C Favored Angle screwdriver (FW069R)
  - C1/C2 drill bit Ø 2.4 mm for Ø 3.5 mm screws (FW662SU) **M**
  - C1/C2 screw tap Ø 3.5 mm (FW663R) **N**
  - C1/C2 inner sleeve guide Ø 3.5 mm (FW661R) **L**
  - Apfelbaum ball end screwdriver (FJ988R)

### Note

K-wires generally may not be used with the S<sup>4</sup>C system.

## S<sup>4</sup> Cervical - Navigated Instruments

### Preparing holes for S<sup>4</sup>C screws with navigation



**Risk of injury to the patient!**  
 ➤ Observe the combination specifications

To center punch the screw holes in the cortical layer for the self-tapping S<sup>4</sup>C screws Ø 3.5 mm with navigation, use the S<sup>4</sup>C navigated drillguide Ø 3.5 mm F only together with S<sup>4</sup>C cortical punch for S<sup>4</sup>C navigated drill guide O.

To center punch screw holes in the cortical layer without navigation, see instructions for use S<sup>4</sup> Cervical Instruments (TA011984).



**Risk of damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue when inserting the cortical punch without drill guide!**  
 ➤ Use the cortical punch only with drill guide FW654R.

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 of the Aesculap star unit G against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C drill guide F. When doing so, ensure that the pin of the adapter 3 engages in the recess on the star unit.
- Release locking sleeve 1.

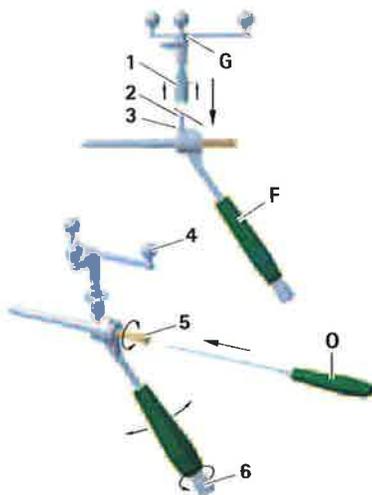


Fig. 1 Mounting the Aesculap star unit on S<sup>4</sup>C drill guide FW654R

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the cortical punch O for navigated drill guide is removed.
- To ensure the camera has an unrestricted view on the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the S<sup>4</sup>C drill guide F and turn the Aesculap star unit G to the desired position.
- Once the desired position is reached, tighten knob 6 again.
- Adjust the center punch depth by turning the depth stop 5 on the S<sup>4</sup>C drill guide F. The maximum depth is 6 mm.
- Insert S<sup>4</sup>C cortical punch O into S<sup>4</sup>C drill guide F.
- Check the pre-set center punch depth with a caliper (e.g. AA845R).
- To open the cortical bone, press S<sup>4</sup>C cortical punch to the preset depth under control with the Brainlab navigation system.

### Drilling holes for the S<sup>4</sup>C screws



**Risk of injury from an incorrectly placed hole or a hole that is too deep!**

- Do not sharpen the drill, as this would cause imprecise or incorrect readings on the depth gauge.
- Replace blunt drills with new ones.

The drill is applied with a S<sup>4</sup>C drill guide and drilled in either manually with the drill handle (FJ839R) or with a motor system with the Aesculap Intra-handpiece (e.g. GD450R/GD456R).

### Assembling the drill and drill handle (for manual drilling only)



**Risk of damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue through incorrect drilling!**

- Use only the correct S<sup>4</sup>C drill guides to drill holes. Insert drill only with the correct drill guide.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AA845R, Caspar instrument for anterior cervical fusion).



**Injury to spinal cord and nerve roots caused by application of a drill that is too long!**

- Use the X-ray image to select an appropriate drill length prior to the operation.
- The drill may only be aligned and inserted under radiographic control and/or with the aid of a navigation system.
- Select a drill of a length equivalent to the intended drill hole depth.

- Insert drill in the drill handle (FJ839R), see Fig. 2.
  - Retract and hold locking sleeve against the spring pressure in the direction of the arrow.
  - Push the drill into the receptacle of the drill handle as far as it will go.
  - Slightly rotate the drill and release locking sleeve.
- The drill engages audibly, see Fig. 2.

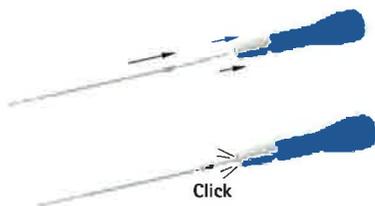


Fig. 2 Assembling the drill



**Risk of injury and/or damage to the drill if the drill rotation speed is too high!**

- Use the lowest drilling speed possible, so that you can control the drilling depth.
- Do not bend the drill during the drilling process.

#### Drilling holes for S<sup>4</sup>C screws Ø 3.5 mm



**Risk of injury to the patient!**

- Observe the combination specifications

For controlled drilling of the holes for S<sup>4</sup>C-screws Ø 3.5 mm with standard drill Ø 2.4 mm (FW051SU), the S<sup>4</sup>C navigated drill guide Ø 3.5 mm F (FW654R) must always be used.

*Note*

The drill Ø 2.9 mm (FW052SU) may not be used with S<sup>4</sup>C navigated drill guide F.

To drill the holes for the screws with Ø 4 mm, use standard drill guide FW053R without navigation, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 of the Aesculap star unit G against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C drill guide F. When doing so, ensure that the pin of the adapter 3 engages in the recess on the star unit.
- Release locking sleeve 1.

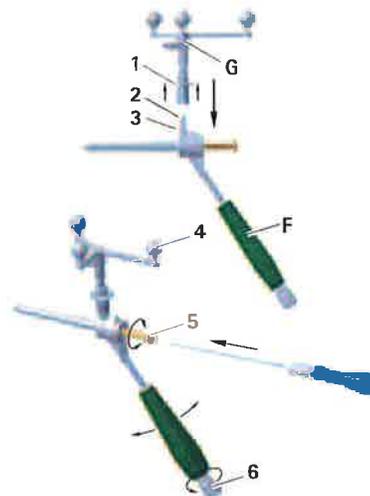


Fig. 3 Mounting the Aesculap star unit on S<sup>4</sup>C drill guide FW654R

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the drill FW051SU is removed.
- To ensure the camera has an unrestricted view on the reflective marker spheres, unscrew knob 6 on the handle of the S<sup>4</sup>C drill guide F and turn the Aesculap star unit G to the desired position, see Fig. 1.
- Once the desired position is reached, tighten knob 6 again.
- Adjust the drill depth by turning the depth stop 5 on the S<sup>4</sup>C drill guide F.
- Insert the drill with mounted handle or Intra-handpiece into S<sup>4</sup>C drill guide F.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AA845R, Caspar instrument for anterior cervical fusion).
- Drill to the pre-set depth under control with the Brainlab navigation system.

**S<sup>4</sup> Cervical - Navigated Instruments**

**Tapping (optional)**

S<sup>4</sup>C screws are self-tapping. However, if the bone quality is found to be hard during the operation, the surgeon can also pre-tap the thread with the S<sup>4</sup>C screw tap.

- For navigated tapping of the drill holes for screws Ø 3.5 mm, use S<sup>4</sup>C navigated screw tap A.
- For tapping the drill holes for screws Ø 4 mm, use the standard screw tap without navigation (FW047R), see TA011984.



**Risk of tissue injury when using the S<sup>4</sup>C screw tap (A) and damage to bone thread!**

- Prior to using the S<sup>4</sup>C screw tap, ensure that the moveable sleeve of the screw tap retracts correctly.

- Mount the Brainlab reflective marker spheres 4 onto the IGS Tool Star Unit B (pre-calibrated), see Brainlab user manual.
- Push the IGS Tool Star Unit onto the shaft 7 of the S<sup>4</sup>C navigated screw tap A. Ensure that the star unit is securely fitted onto the shaft of the S<sup>4</sup>C screw tap.

*Note*

The star unit can be rotated on the shaft of the S<sup>4</sup>C screw tap.

- Retract and hold locking sleeve 8 against the spring pressure.
- Attach S<sup>4</sup>C handle (FW067R or FW165R) to S<sup>4</sup>C navigated screw tap A.
- Push S<sup>4</sup>C handle onto the shaft of the S<sup>4</sup>C navigated screw tap A.
- Release locking sleeve 8, see Fig. 4.

Check that the S<sup>4</sup>C handle is engaged.

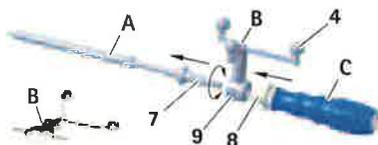


Fig. 4 Mounting the IGS Tool Star Unit and S<sup>4</sup>C handle onto the S<sup>4</sup>C screw tap



**Risk of injury to the patient!**

- Before use, ensure that the selected instrument has been correctly assembled.
- Ensure that the arrow on the underside of the IGS Tool Star Unit (pre-calibrated) is pointing to the tip of the tool.

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 5th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.

- To tap the thread, hold the IGS Tool Star Unit B at the planned indentations with one hand, and with the other hand screw in S<sup>4</sup>C handle C slowly and steadily under control with the Brainlab navigation system, until the required depth is reached.
- Use the scale behind the retractable sleeve of the S<sup>4</sup>C screw tap to read the depth during the tapping process, see Fig. 5.



Fig. 5 Screw tap with readable thread depth

**Positioning S<sup>4</sup>C screw under navigation and temporarily fixing it in place**



**Risk of injury to the patient!**

- Use S<sup>4</sup>C screwdriver only with IGS Tool Star Unit ML for manual calibration.
- If you change screws, perform the calibration again.

- To position S<sup>4</sup>C screws Ø 3.5 mm and Ø 4 mm under navigation, use S<sup>4</sup>C navigated screwdriver D.
- Mount the Brainlab reflective marker spheres 4 onto IGS Tool Star Unit ML E, see Brainlab user manual.
- Push the IGS Tool Star Unit ML E onto the shaft 10 of the S<sup>4</sup>C screwdriver D. Ensure that the star unit is securely fitted onto the shaft of the S<sup>4</sup>C screwdriver.

*Note*

The star unit can be rotated on the shaft of the S<sup>4</sup>C screwdriver.

- Retract and hold locking sleeve B against the spring pressure.
- Mount S<sup>4</sup>C handle (FW067R or FW165R) onto S<sup>4</sup>C screwdriver D.
- Push S<sup>4</sup>C handle onto the shaft of S<sup>4</sup>C screwdriver D.
- Release locking sleeve B, see Fig. 6.

Check that the S<sup>4</sup>C handle is engaged.

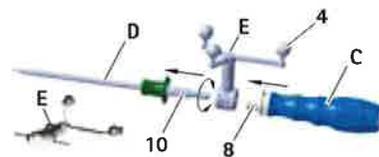


Fig. 6 Mounting the IGS Tool Star Unit and S<sup>4</sup>C handle (FW067R or FW165R) onto the S<sup>4</sup>C screwdriver



**Note**

The S<sup>4</sup>C screwdriver is fitted with a self-retaining function to prevent the S<sup>4</sup>C screw from falling off when it is passed to the surgeon.

- Retract and hold holding sleeve 12 on the S<sup>4</sup>C screwdriver D.
- Insert the tip of the S<sup>4</sup>C screwdriver D fully into the hexagon of the screw 11.
- Release holding sleeve 12.

Ensure that the screw 11 is securely in place on the S<sup>4</sup>C screwdriver D and that the polyaxiality of the screw 11 is blocked.

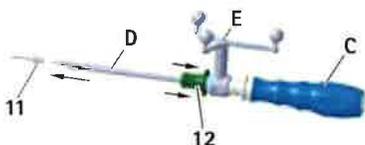


Fig. 7 Picking up the S<sup>4</sup>C screw with the S<sup>4</sup>C screwdriver



**Risk of injury to the patient!**

- Before use, ensure that the selected instrument has been correctly assembled.
- Ensure that the arrow on the underside of the IGS Tool Star Unit ML is pointing to the tip of the tool.

- Prior to using the instrument with the correctly held screw, perform manual calibration with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Screw in the screw under control with the Brainlab navigation system. When doing so, hold IGS Tool Star Unit ML at the planned indentations with one hand, and turn the S<sup>4</sup>C handle C to screw in the screw 11 with the other hand.

**Smooth-shank screw instruments**



**Risk of injury to the patient!**

- Observe the combination specifications

Instruments for smooth-shank screws are marked with a light-blue ring. They are used to center punch, drill and tap holes for smooth-shank screws Ø 4 mm.



Serious complications for the patient can be caused by incorrect positioning of instruments or implants!

- Carry out operative steps with radiographic visualization.
- When removing the smooth-shank screw awl (FW085R) and during the further operating steps, ensure that the S<sup>4</sup>C navigated smooth-shank screw guide sleeve remains securely fixed in place.
- Ensure that the window on the S<sup>4</sup>C navigated smooth-shank screw guide sleeve is closed during the preparation of the screw hole and while the screw is being inserted, see laser marking on the inner sleeve.
- Take care that no tissue gets caught when opening and closing the window on the S<sup>4</sup>C navigated smooth-shank screw guide sleeve, after the screw has been put in place.

- Mount the Brainlab reflective marker spheres 4 onto the Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2. When doing so, ensure that the recess on the star unit is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

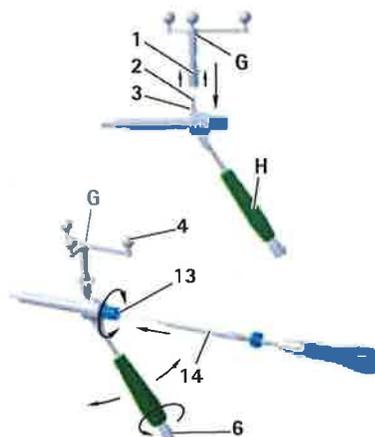


Fig. 8 Mounting the Aesculap star unit on the S<sup>4</sup>C guide sleeve for smooth-shank screws.

## S<sup>4</sup> Cervical - Navigated Instruments



### Risk of injury to the patient!

- Slide reduction sleeve into the Brainlab Instrument Calibration Matrix Rev. 4, until you hear an audible click.

- Prior to each use, check the instrument with special reduction sleeve I with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with reduction sleeve I with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that all other instruments (awl, drill, screw tap etc.) are removed for the instrument validation.



Fig. 9 Reduction sleeve for validation/verification with the Brainlab Instrument Calibration Matrix Rev. 4

- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the S<sup>4</sup>C guide sleeve H and turn the Aesculap star unit G to the desired position, see Fig. 8.
- Once the desired position is reached, tighten knob 6 again.
- Place S<sup>4</sup>C guide sleeve H for smooth-shank screws in the operating field. When doing so, ensure that the window of the guide sleeve is closed during the preparation and insertion of the screw with the guide sleeve, see laser marking on the inner sleeve 13.
- Center punch the cortical layer of the vertebral body with the smooth-shank screw awl (FW085R), see TA011984.
- If necessary, insert the awl into the inner sleeve 13 and center punch the bone as far as the stop-position. The stop-position is indicated with a marking on the awl.
- Remove the awl from the operating field.
- Insert the smooth-shank screw drill (FW086SU) 14 with mounted handle (FJ839R) or Intra-handpiece into the inner sleeve 13.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AAB45R, Caspar instrument for anterior cervical fusion).
- Under control with the Brainlab navigationssystem, drill a hole in the bone until the adjustable stop-position is reached. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).
- Remove the drill from the operating field.
- To prepare the drill holes for the screws, tap the thread with the smooth-shank screw tap (FW087R).

- Insert the smooth-shank screw tap into the inner sleeve and slowly and steadily screw in until the desired depth. When doing so, read the thread depth on the screw tap scale.
- Remove smooth-shank screw tap from the operating field.

### Note

If the S<sup>4</sup>C screw with S<sup>4</sup>C screwdriver FW656R is planned to be inserted under navigation with the guide sleeve H, remove the Aesculap star unit on the S<sup>4</sup>C guide sleeve for smooth-shank screws.



### Risk of injury to the patient!

- The navigated S<sup>4</sup>C screwdriver FW656R or other screwdrivers are only intended for navigation in the non-navigated S<sup>4</sup>C guide sleeve FW658R.
- Navigate the S<sup>4</sup>C screwdriver FW656R, see positioning S<sup>4</sup>C screw under navigation and temporarily fix it in place.



### Risk of injury to the patient through freely rotating screws!

- Do not screw in screw so far that the screw head comes into contact with the S<sup>4</sup>C guide sleeve.

### Note

Use navigated S<sup>4</sup>C screwdriver FW656R only with non-navigated S<sup>4</sup>C guide sleeve FW658R.

- Navigate S<sup>4</sup>C screwdriver, see Positioning S<sup>4</sup>C screw under navigation and temporarily fixing it in place.
- Insert the screw through the S<sup>4</sup>C guide sleeve but do not screw it in completely (smooth shank must remain free). Remove S<sup>4</sup>C screwdriver D from the operating field.
- Remove instrument from the screw:
  - Turn the blue inner sleeve 13 and open the window on the S<sup>4</sup>C guide sleeve.
  - Carefully push away S<sup>4</sup>C guide sleeve H laterally from the screw.
  - Remove S<sup>4</sup>C guide sleeve H from the operating field.



### Instruments for Favored Angle screws



**Risk of injury to the patient!**

- Observe the combination specifications

Favored Angle instruments are marked with a gold-colored ring.



**Serious complications for the patient can be caused by incorrect positioning of instruments or implants!**

- Carry out operative steps with radiographic visualization.
- When removing the obturator (FJ983R) and during the further operating steps, ensure that the S<sup>4</sup>C guide sleeve remains securely fixed in place.

### Drilling holes for Favored Angle screws

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Mount Aesculap star unit G onto S<sup>4</sup>C navigated guide sleeve Ø 3.5/ 4.0 mm J. When doing so, retract and hold the locking sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C guide sleeve J. When doing so, ensure that the recess is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

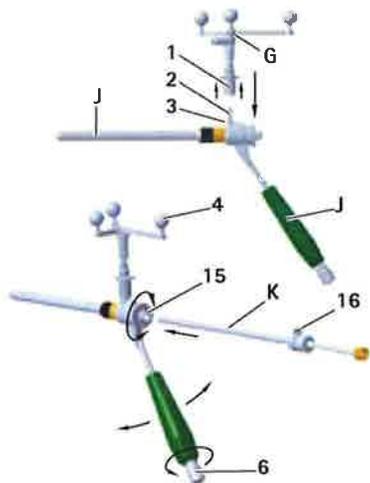


Fig. 10 Mounting the Aesculap star unit onto the S<sup>4</sup>C guide sleeve; inserting the S<sup>4</sup>C drill guide

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide K is mounted prior to this check.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide K is mounted prior to this validation.
- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the S<sup>4</sup>C guide sleeve J and turn the Aesculap star unit G to the desired position, see Fig. 10.
- Once the desired position is reached, tighten knob 6 again.
- Then remove inner sleeve guide K again from the S<sup>4</sup>C guide sleeve J.
- Slide obturator (FJ983R) into the inner sleeve 15 of the S<sup>4</sup>C guide sleeve J.  
The obturator engages in the inner sleeve and can still be rotated.
- Bring S<sup>4</sup>C guide sleeve J with mounted obturator into the operating field through the stab incision and position it in place.
- Press the button 16 on the obturator (FJ983R) and withdraw the obturator from the inner sleeve 15.
- If necessary, slide Apfelbaum trocar (FJ984R) into the inner sleeve 15 and insert into the bone to center punch the screw entry point.
- Remove the trocar from the operating field.
- Push inner sleeve guide K onto the inner sleeve 15.  
The inner guide sleeve engages on the inner sleeve and can still be rotated, see Fig. 10.
- Insert drill for Favored Angle screws (FW088SU) with mounted handle (FJ839R) or Intra-handpiece into the inner sleeve guide K.
- Drill to the pre-set depth under control with the Brainlab navigation system. The drill depth can be read on the scale on the inner sleeve guide K. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).

#### Note

*So as not to lose the entry opening, keep the drill in the drill hole, press the button 16 on the inner sleeve guide K and push down the guide sleeve until it reaches the stop on the bone surface. Then remove the drill and inner sleeve guide K from the S<sup>4</sup>C guide sleeve J.*

- Press button 16 and remove the inner sleeve guide K from the inner sleeve 15.
- To prepare screw holes, insert the Favored Angle screw tap Ø 4 mm (FW089R) into the inner sleeve 15 and tap. The drill depth can be read on the scale on the screw tap.
- Turn the screw tap counterclockwise until it almost exits the bone.

## S<sup>4</sup> Cervical - Navigated Instruments

**Note**

So as not to lose the entry opening, turn the screw tap counterclockwise until it almost exits the bone. Then turn the inner sleeve 15 counterclockwise and at the same time push down the S<sup>4</sup>C guide sleeve J until it reaches the stop on the bone surface. After that, completely unscrew the Favored Angle tap Ø 4 mm (FW089R) from the bone and together with the inner sleeve 15 remove it from the S<sup>4</sup>C guide sleeve J.

**Inserting the screw**

- Ensure that the inner sleeve 15 has been removed from the S<sup>4</sup>C guide sleeve J by turning it counterclockwise.
- Pick up a suitable Favored Angle screw Ø 4.0 mm with the self-retaining S<sup>4</sup>C screwdriver (FW069R). When doing so, retract and hold the holding sleeve 12 against the spring pressure.

**Note**

The self-retaining function of the instrument prevents the screw from falling off of the S<sup>4</sup>C screwdriver when it is being passed to the operating surgeon

- Press the working end of the S<sup>4</sup>C screwdriver fully into the hexagon of the screw 11.
- Release the holding sleeve 12.
- Screw in the screw under control with the Brainlab navigation system.
- Tighten the screw. When doing so, work through the S<sup>4</sup>C guide sleeve.
- Activate the holding sleeve 12 and release the S<sup>4</sup>C screwdriver from the screw.
- Remove the S<sup>4</sup>C guide sleeve and S<sup>4</sup>C screwdriver from the operating field.

**Standard screw (Ø 3.5 mm) instrumentation with Favored Angle instruments**



**Risk of injury to the patient!**  
➤ Observe the combination specifications

To insert standard screws Ø 3.5 mm with the Favored Angle instruments, instruments L, M and N must also be used. These instruments are marked with a black ring.



**Serious complications for the patient can be caused by incorrect positioning of instruments or implants!**

- Carry out operative steps with radiographic visualization.
- When removing the obturator (FJ983R) and during the further operating steps, ensure that the guide sleeve remains securely fixed in place.
- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Mount Aesculap star unit G onto S<sup>4</sup>C navigated guide sleeve Ø 3.5/ 4.0 mm J. When doing so, retract and hold the securing sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C guide sleeve J. When doing so, ensure that the recess is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

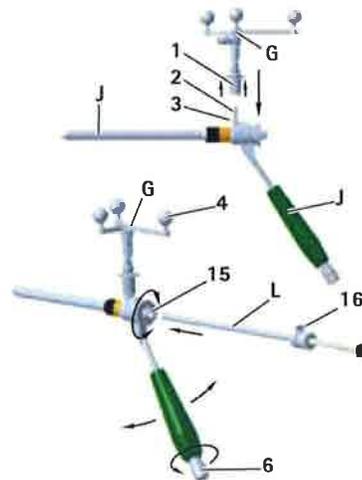


Fig. 11 Mounting the Aesculap star unit onto the S<sup>4</sup>C guide sleeve; inserting the S<sup>4</sup>C drill guide

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide L is mounted prior to this check.



- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide **L** is mounted prior to this validation.
- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob **6** on the S<sup>4</sup>C handle of the navigated S<sup>4</sup>C guide sleeve **J** and turn the Aesculap star unit **G** to the desired position, see Fig. 11.
- Once the desired position is reached, tighten the knob **6** again.
- Then remove inner sleeve guide **L** again from the guide sleeve **J**.
- Slide obturator (FJ983R) into the inner sleeve **15** of the S<sup>4</sup>C guide sleeve **J**. The obturator engages in the inner sleeve and can still be rotated.
- Bring S<sup>4</sup>C guide sleeve **J** with mounted obturator into the operating field through the stab incision and position it in place.
- Press the button **16** on the obturator (FJ983R) and withdraw the obturator from the inner sleeve **15**.
- If necessary, slide Apfelbaum trocar (FJ984R) into the inner sleeve **15** and insert into the bone to center punch the screw entry point.
- Remove the trocar from the operating field.
- Push inner sleeve guide **L** onto the inner sleeve **15**. The inner guide sleeve engages on the inner sleeve and can still be rotated, see Fig. 11.
- Insert drill  $\varnothing$  2.4 mm **M** with mounted handle (FJ839R) or Intra-hand-piece into the inner sleeve guide **L**.
- Drill to the pre-set depth under control with the Brainlab navigation system. The drill depth can be read on the scale on the inner sleeve guide **L**. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).

#### Note

*So as not to lose the entry opening, keep the drill in the drill hole, press the button **16** on the inner sleeve guide **L** and push down the guide sleeve until it reaches the stop on the bone surface. Then remove drill and inner sleeve guide **L** from the S<sup>4</sup>C guide sleeve **J**.*

- Press button **16** and remove inner sleeve guide **L** from the inner sleeve **15**.
- To prepare screw holes, insert the C1/C2 screw tap  $\varnothing$  3.5 mm **N** into the inner sleeve **15** and tap. The drill depth can be read on the scale on the screw tap.

#### Note

*So as not to lose the entry opening, turn the screw tap counterclockwise until it almost exits the bone. Then turn the inner sleeve **15** counterclockwise and at the same time push down the S<sup>4</sup>C guide sleeve **J** until it reaches the stop on the bone surface. After that, completely unscrew tap **N** from the bone and together with the inner sleeve **15** remove it from the S<sup>4</sup>C guide sleeve **J**.*

#### Inserting the screw

- Ensure that the inner sleeve **15** has been removed from the S<sup>4</sup>C guide sleeve **J** by turning it counterclockwise.
- Pick up a suitable standard screw  $\varnothing$  3.5 mm with the self-retaining S<sup>4</sup>C screwdriver (FW069R). When doing so, retract and hold the holding sleeve **12** against the spring pressure.

#### Note

*The self-retaining function of the instrument prevents the screw from falling off of the S<sup>4</sup>C screwdriver when it is being passed to the operating surgeon.*

- Press the working end of the S<sup>4</sup>C screwdriver fully into the hexagon of the screw **11**.
- Release the holding sleeve **12**.
- Screw in the screw under control with the Brainlab navigation system.
- Tighten the screw. When doing so, work through the S<sup>4</sup>C guide sleeve.
- Activate the holding sleeve **12** and release the S<sup>4</sup>C screwdriver from the screw.
- Remove the S<sup>4</sup>C guide sleeve and S<sup>4</sup>C screwdriver from the operating field.

## S<sup>4</sup> Cervical - Navigated Instruments

### Disassembling

#### S<sup>4</sup>C navigated screw tap Ø 3.5 mm, FW655R

- Loosen nut 19 and unscrew from the sleeve 17.
- Remove sleeve 17 together with spring 18 in the direction of the arrow.

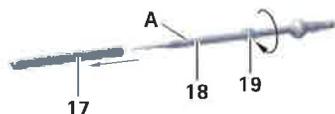


Fig. 12 Disassembling the S<sup>4</sup>C screw tap

#### S<sup>4</sup>C navigated screwdriver, FW656R

- Retract and hold green holding sleeve 22 against the spring pressure.
- Unscrew screw sleeve 20 at the working end of the S<sup>4</sup>C screwdriver and remove it from the shaft.
- Release green holding sleeve 22.
- Push the green holding sleeve 22 with the retaining tongues in the direction of the instrument's working end and remove it from the screwdriver shaft.

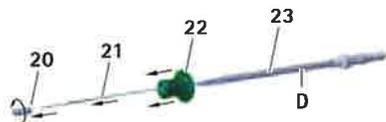


Fig. 13 Disassembling the S<sup>4</sup>C screwdriver

#### S<sup>4</sup>C navigated drill guide Ø 3.5 mm, FW654R

- Turn guide sleeve 24 clockwise and remove it. Be aware that it is a left-handed thread.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.



Fig. 14 Disassembling the S<sup>4</sup>C drill guide

#### S<sup>4</sup>C navigated guide sleeve for smooth-shank screws, FW658R

- Turn inner sleeve 26 to the "remove" position and remove it from the outer sleeve in the direction of the arrow.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.

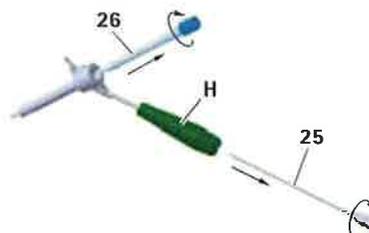


Fig. 15 Disassembling the guide sleeve

#### S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm, FW660R

- Loosen inner sleeve 27 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.

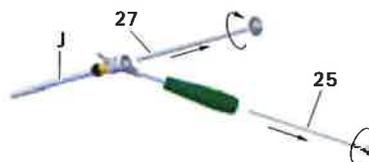


Fig. 16 Disassembling the guide sleeve

### Assembling

#### S<sup>4</sup>C navigated screw tap Ø 3.5, FW655R

- Push guide sleeve 17 together with spring 18 onto the S<sup>4</sup>C navigated screw tap A in the direction of the arrow and turn nut 19 clockwise to tighten it.

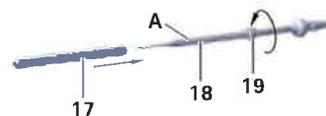


Fig. 17 Assembling the S<sup>4</sup>C navigated screw tap



**S<sup>4</sup>C navigated screwdriver, FW656R**



The S<sup>4</sup>C screwdriver will not function properly if the retaining tongues are bent or kinked!

- Do not bend or kink the retaining tongues.

- Push green holding sleeve 22 with retaining tongues 21 onto the screwdriver shaft so that the retaining tongues engage in the grooves 23 of the screwdriver shaft.
- Retract and hold green holding sleeve 22 against the spring pressure.
- Screw screw sleeve 20 onto the working end of the S<sup>4</sup>C screwdriver D and tighten it.
- Release green holding sleeve 22.



Fig. 18 Assembling the S<sup>4</sup>C screwdriver

**S<sup>4</sup>C navigated drill guide Ø 3.5 mm, FW654R**

- Screw on guide sleeve 24 counterclockwise. Be aware that it is a left-handed thread. You will hear and feel the guide sleeve clicking into position every half turn.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.

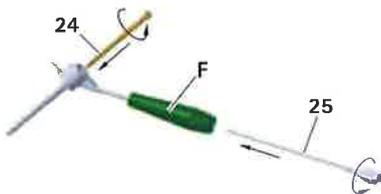


Fig. 19 Assembling the S<sup>4</sup>C drill guide

**S<sup>4</sup>C navigated guide sleeve for smooth-shank screws, FW658R**

- Insert inner sleeve 26 into the outer sleeve in the direction of the arrow in the "remove" position.
- Then turn to "closed" position.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.

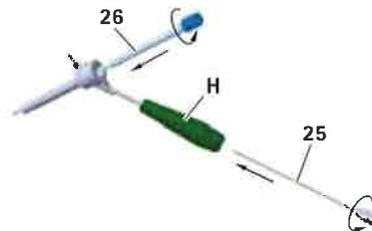


Fig. 20 Assembling the guide sleeve

**S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm, FW660R**

- Push inner sleeve 27 into the outer sleeve in the direction of the arrow, screw in clockwise and tighten it.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.

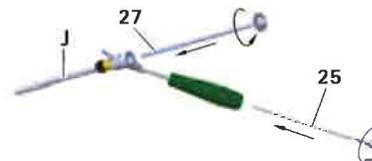


Fig. 21 Assembling the guide sleeve

**Validated reprocessing procedure**

*Note*

National laws, national and international standards and directives, and product-specific hygiene regulations for reprocessing must be observed.

*Note*

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

*Note*

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

## S<sup>4</sup> Cervical - Navigated Instruments

### Note

It should be noted that successful reprocessing of this medical device can only be guaranteed following prior validation of the reprocessing method. The operator/sterile processing technician is responsible for this.

### Note

Up-to-date information on reprocessing can be found on the Aesculap Extranet at [www.aesculap-extra.net](http://www.aesculap-extra.net)

### Single-use products



**Risk of infection of patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!**

➤ **Do not reprocess the product.**

The following products may not be reprocessed.:

- S<sup>4</sup>C C1/C2 drill bit Ø 2.4 mm (FW662SU)
- Standard drill Ø 3.5 mm (FW051SU)
- Favored Angle screw drill (FW088SU)
- Smooth-shank screw drill (FW086SU)

### General information

To prevent increased contamination of loaded instrument trays during use, please ensure that contaminated instruments are collected separately and not returned to the instrument tray.

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion of stainless steel. Therefore the time interval between application and processing should not exceed 6 h; also, neither fixating pre-cleaning 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.

Only process chemicals that have been tested and approved (e.g. VAH/ DGHM 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 regarding temperature, concentration and contact time should 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 process chemicals that cause stress cracks or brittleness in plastics.
- Clean the product immediately after use.

Please see [www.a-k-i.org](http://www.a-k-i.org) for more detailed information on hygienically safe reprocessing which is protective of materials and retains their value.

- Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. To prevent foam formation and diminished effectiveness of the process chemicals: Prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water.

### Preparations at the place of use

- Disassemble the product immediately after use, as described in the respective instructions for use.
- Open all valves/faucets.
- Rinse surfaces inaccessible to visual inspection, e.g. in products with hidden gaps or lumens or products with complex geometries, preferably with distilled water, using e.g. a disposable syringe.
- 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.

### Preparation before cleaning

- Disassemble the product prior to cleaning, see Disassembling.

### Cleaning/disinfection



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

- Use the cleaning/disinfectant agent according to manufacturer instructions.
- Observe specifications regarding concentration, temperature, and exposure time.
- Do not exceed the maximum allowable cleaning temperature of 55 °C.



➤ Carry out ultrasound cleaning:

- as an effective mechanical supplement to manual cleaning/disinfection.
- as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfection.
- as an integrated mechanical support measure for mechanical cleaning/disinfection.
- for additional cleaning of products with residues left after mechanical cleaning/disinfection.

*Note*

For cleaning and disinfecting the IGS Tool Star Unit (pre-calibrated) and the IGS Tool Star Unit ML (calibration with ICM4), see Brainlab user manual.

**FW652R, FW654R, FW658R, FW660R, FW661R and FJ985R**



**Danger to the patient!**

- **Only mechanically clean the product.**

*Note*

Listed below are the reprocessing procedures approved for the individual system components.

**Manual cleaning with immersion disinfection**

Art. no.	Designation
FW067R	Handle without ratchet <b>C</b>
FW165R	Handle with ratchet <b>C</b>
FW653R	Cortical punch for navigated drill guide FW654R <b>O</b>
FW655R	Navigated screw tap Ø 3.5 mm <b>A</b>
FW656R	Navigated screwdriver for polyaxial screw <b>D</b>
FW657R	Reduction sleeve Ø 13 mm for calibration unit <b>I</b>
FW663R	C1/C2 screw tap Ø 3.5 mm <b>N</b>

**Mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FW653R	Cortical punch for navigated drill guide FW654R <b>O</b>
FW657R	Reduction sleeve Ø 13 mm for calibration unit <b>I</b>
FW663R	C1/C2 screw tap Ø 3.5 mm <b>N</b>

**Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FW652R	Aesculap star unit navigation attachment <b>G</b>
FW654R	Navigated drill guide Ø 3.5 mm, short <b>F</b>
FW655R	Navigated screw tap Ø 3.5 mm <b>A</b>
FW656R	Navigated screwdriver for polyaxial screw <b>D</b>
FW658R	Navigated guide sleeve Ø 4.0 mm for smooth-shank screws <b>H</b>
FW660R	Navigated guide sleeve Ø 3.5/4.0 mm <b>J</b>

**Manual pre-cleaning with ultrasound and brush, and subsequent mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FJ985R	C1/C2 inner sleeve guide Ø 4 mm <b>K</b>
FW661R	C1/C2 inner sleeve guide Ø 3.5 mm <b>L</b>

**Manual cleaning/disinfection**

- Keep working ends open for cleaning.
- When cleaning instruments with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.
- After manual cleaning/disinfection, check visible surfaces visually for residues.
- Repeat the cleaning process if necessary.

## S<sup>4</sup> Cervical - Navigated Instruments

### Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Disinfectant Cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Disinfection	RT (cold)	15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
IV	Final rinse	RT (cold)	1	-	FD-W	-
V	Drying	RT	-	-	-	-

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

RT: Room temperature

#### Phase I

- Fully immerse the product in the cleaning/disinfecting solution for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the instrument under running tap water with a suitable cleaning brush where necessary for as long as it takes to remove all discernible residues.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/Ø: 4.5, e.g. TA011944 and brush length: 20/Ø: 2.5, e.g. TE654202 and brush length: 50/Ø: 10, e.g. TA007747) for at least 1 min. or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, joints, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution (at least five times), using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

#### Phase II

- Rinse/flush the instrument 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 instrument in the disinfectant solution.
- Mobilize non-rigid components, such as set screws, joints, etc. during disinfection.
- Rinse lumens at least 5 times at the beginning of the exposure time, using a disposable syringe (20 ml) and an appropriate rinsing adapter. Ensure that all accessible surfaces are moistened.
- Drain any remaining water fully.

#### Phase IV

- Rinse/flush the instrument thoroughly (all accessible surfaces).
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens at least 5 times, using a disposable syringe (20 ml) and an appropriate rinsing adapter.
- Drain any remaining water fully.

#### Phase V

- Dry the instrument with a lint-free cloth or medical compressed air.



**Mechanical cleaning/disinfecting**

Note

The disinfectant must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark).

Note

Ensure  $A_0 > 3$  000 for the process. The disinfectant used for processing must be serviced and checked at regular intervals.

Note

The disinfectant used for processing must be serviced and checked at regular intervals.

- Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Connect components with lumens and channels directly to the rinsing port of the injector carriage.
- Place instruments in the tray with their hinges open.

**Mechanical alkaline cleaning and thermal disinfection**

Machine type: Single-chamber cleaning/disinfection device without ultrasound

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	BBRAUN HELIMATIC CLEANER alkaline with tensides, application solution 0.5%
III	Intermediate rinse	>10/50	1	FD-W	-
IV	Thermal disinfection	90/194	5	FD-W	-
V	Drying	-	-	-	According to disinfectant program

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)



## S<sup>4</sup> Cervical - Navigated Instruments

### Mechanical cleaning/disinfection with manual pre-cleaning

*Note*

The disinfectant must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO15883).

*Note*

Ensure  $Ao > 3\ 000$  for the process. The disinfectant used for processing must be serviced and checked at regular intervals.

*Note*

The disinfectant used for processing must be serviced and checked at regular intervals.

### Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Disinfectant Cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Rinsing	RT (cold)	1	-	D-W	-

D-W: Drinking water

RT: Room temperature

#### Phase I

- Fully immerse the product in the cleaning/disinfecting solution for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/∅: 4.5, e.g. TA011944 and brush length: 20/∅: 2.5, e.g. TE654202 and brush length: 50/∅: 10, e.g. TA007747) for at least 1 min or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- After cleaning, thoroughly rinse through these components (at least five times) with the cleaning solution, using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

#### Phase II

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



#### Manual pre-cleaning with ultrasound and brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Ultrasonic cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Rinsing	RT (cold)	1	-	D-W	-

D-W: Drinking water

RT: Room temperature

#### Phase I

- Mount jaws protection on the product.
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Remove jaws protection.
- Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/Ø: 4.5, e.g. TA011944 and brush length: 20/Ø: 2.5, e.g. TE654202 and brush length: 50/Ø: 3.8, e.g. TA011327) for at least 1 min or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- After cleaning, use a 20-ml single-use syringe to rinse thoroughly, for at least 5 times, these difficult to access parts of the product.
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

#### Phase II

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

## S<sup>4</sup> Cervical – Navigated Instruments

### Mechanical alkaline cleaning and thermal disinfection

Machine type: Single-chamber cleaning/disinfection device without ultrasound

- Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Keep working ends open for cleaning.
- Place instruments in the tray with their hinges open.

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	BBRAUN HELIMATIC CLEANER alkaline with tensides; application solution 0.5%
III	Intermediate rinse	>10/50	1	FD-W	-
IV	Thermal disinfection	90/194	5	FD-W	-
V	Drying	-	-	-	According to disinfector program

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

### Inspection, maintenance and checks



**Damage (metal seizure/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: Aesculap STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG5989).

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument is: dry, clean, operational, and free of damage (e.g. broken insulation or corroded, loose, bent, broken, cracked, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that still show impurities or contamination.
- Check that the product functions correctly.
- Immediately sort out damaged or inoperative products and have them sent to Aesculap Technical Service, see Technical Service.
- Assemble separable products, see Assembling.
- Check for compatibility with associated products.

### Packaging

- Appropriately protect products with fine working tips.
- Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.
- Pack trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage (DIN EN ISO 11607).

### Sterilization

*Note*

*The product may only be sterilized when dismantled.*

- Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g. by opening any valves and faucets).
- Validated sterilization process
  - Disassemble the instrument.
  - Steam sterilization through fractionated vacuum process
  - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 134 °C/holding time 5 min
- When sterilizing several instruments at the same time in a steam sterilizer, ensure that the maximum permitted load specified by the manufacturer for the steam sterilizer is not exceeded.



**Sterilization for the US market**

- Aesculap does not recommend the device sterilized by flash or chemical sterilization.
- Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle.

To achieve a sterility assurance level of 10<sup>-6</sup>, Aesculap recommends the following parameters:

<b>Aesculap Orga Tray/sterile container (perforated bottom)</b>			
<b>Minimum cycle parameters*</b>			
<b>Sterilization method</b>	<b>Temp.</b>	<b>Time</b>	<b>Minimum drying time</b>
Pre-vacuum	270 °F–275 °F	4 min	20 min

\*Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap sterile container cleared by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

**WARNING for the US market**

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of crosscontamination.

**Storage**

- Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.
- Store sterile packed single-use products dust-protected in a dry, dark and temperature-controlled room.

**Technical Service**



**Risk of injury and/or malfunction!**

- Do not modify the product.

- For service and repairs, please contact your national B. Braun/ Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

**Service addresses**

Aesculap Technical Service  
 Am Aesculap-Platz  
 78532 Tuttlingen / Germany  
 Phone: +49 7461 95-1602  
 Fax: +49 7461 16-5621  
 E-Mail: ats@aesculap.de

Or in the US:

Aesculap Implant Systems, LLC  
 Attn. Aesculap Technical Services  
 615 Lambert Pointe Drive  
 Hazelwood, MO 63042  
 Aesculap Repair Hotline  
 Phone: +1 800 214-3392  
 Fax: +1 314 895-4420

Other service addresses can be obtained from the address indicated above.

**Distributor in the US/Contact in Canada for product information and complaints**

Aesculap Implant Systems, LLC  
 3773 Corporate Parkway  
 Center Valley, PA 18034  
 USA

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**C. SURGICAL TECHNIQUE**

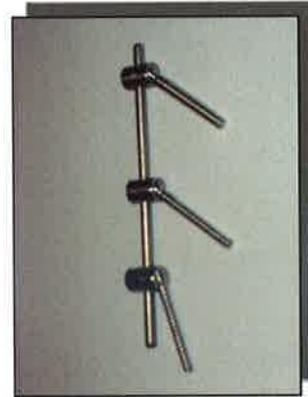
A DRAFT copy of the surgical technique can be found on the following pages.

**DRAFT**

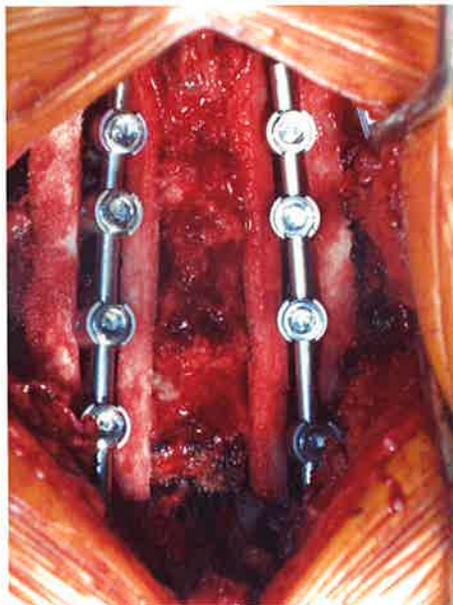
# S<sup>4</sup> Cervical Spinal System

## Navigation

- Screw Application



Description of Instruments  
surgical technique



- **Screw Application**

**DRAFT**

# Pedicle Screw Hole Preparation

The bone awl (FW041R) may be pressed through the cortex to make the entry hole. It has a raised edge 4mm from its tip as a depth marker and to prevent over insertion.



**FW041R**

The handle for short drills (FJ839R) is used to hold the drill during drilling. The desired depth to be drilled is then set on the drill guide (XP650438) by rotating the inner sleeve. The navigated drill guide can only be used for the 3.5mm screw. To drill the holes for the 4.0mm screws, the normal drill guide FW053R must be used.

**FW051SU**



**S4C drill guide 3,5mm navigated XP650438**



The instrument is navigated, for preparation of the screw hole with the drill (position and angle). The tap and the screwdriver are navigated separately (see below).

**DRAFT**

# Pedicle Screw Hole Preparation

The 2.4mm drill (FW051SU) is required for the 3.5mm mini-polyaxial screws.



FW052SU



The 2.9mm drill (FW052SU) is required for the 4.0mm mini-polyaxial screws. The positive stop on the drill for the 4.0mm screws is color coded purple to match the color of the 4.0mm screw body. The drill for the 3.5mm screw is left grey – as for the 3.5mm screw.

The drills are also laser marked clearly according to the size of the screw.

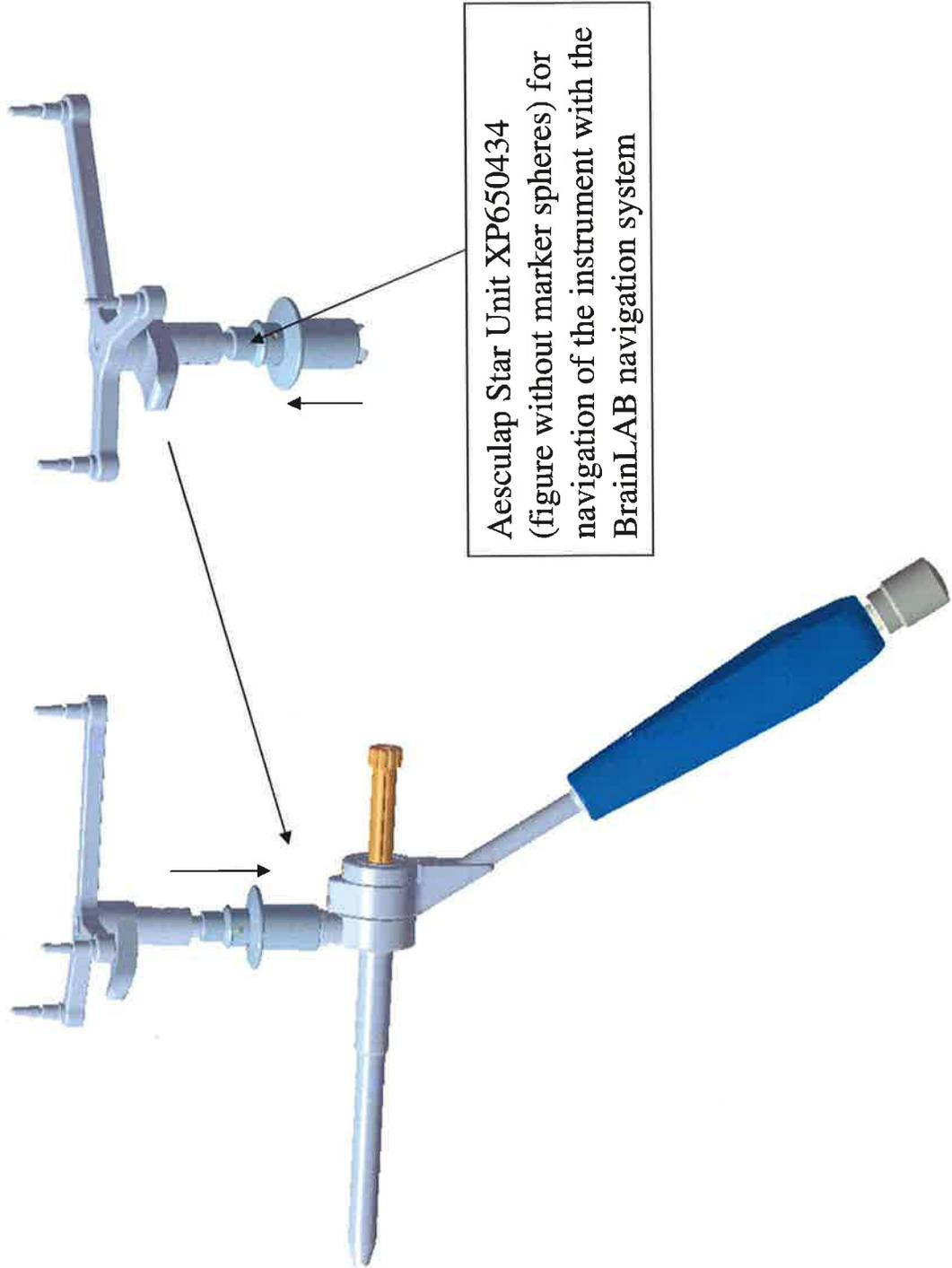
S4C drill guide 3,5mm navigated XP650438

The 2.4mm drill (FW051SU) is inserted into the S4C drill guide 3,5mm navigated (XP650438) up to the positive stop and the exposed length of the drill is verified. The drill guide is then positioned at the desired entry site and the drill advanced to drill the initial pilot hole.

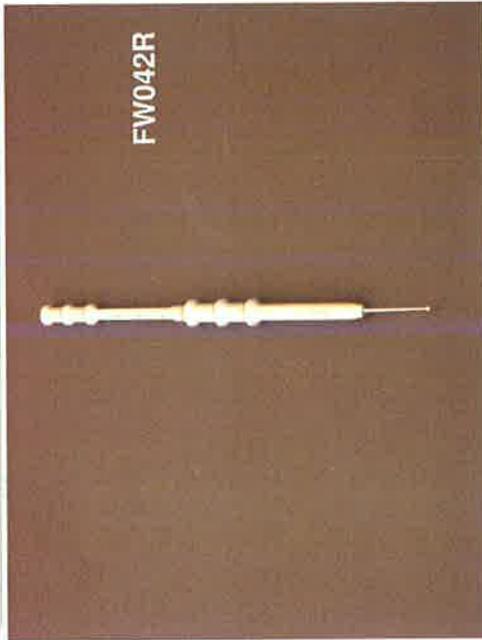
**DRAFT**

**DRAFT**

**S4C DRILL GUIDE NAVIGATED XP650438 with S4C  
BRAINLAB-AESCLAP ADAPTER XP650434**



# Pedicle Screw Hole Preparation



The depth of the drilled hole and the integrity of the pedicle wall could then be confirmed using the pedicle sounder (FW042R). The pedicle sounder shaft is marked in 2mm increments and using the retractable sleeve, it can be used as a gauge to measure the desired depth of the hole to be drilled. The depth displayed reflects the actual screw thread length to be used as well as the depth of the hole in the pedicle, e.g. 24mm depth gauge reading represents not only 24mm drill depth but also 24mm mini-polyaxial screw selection.

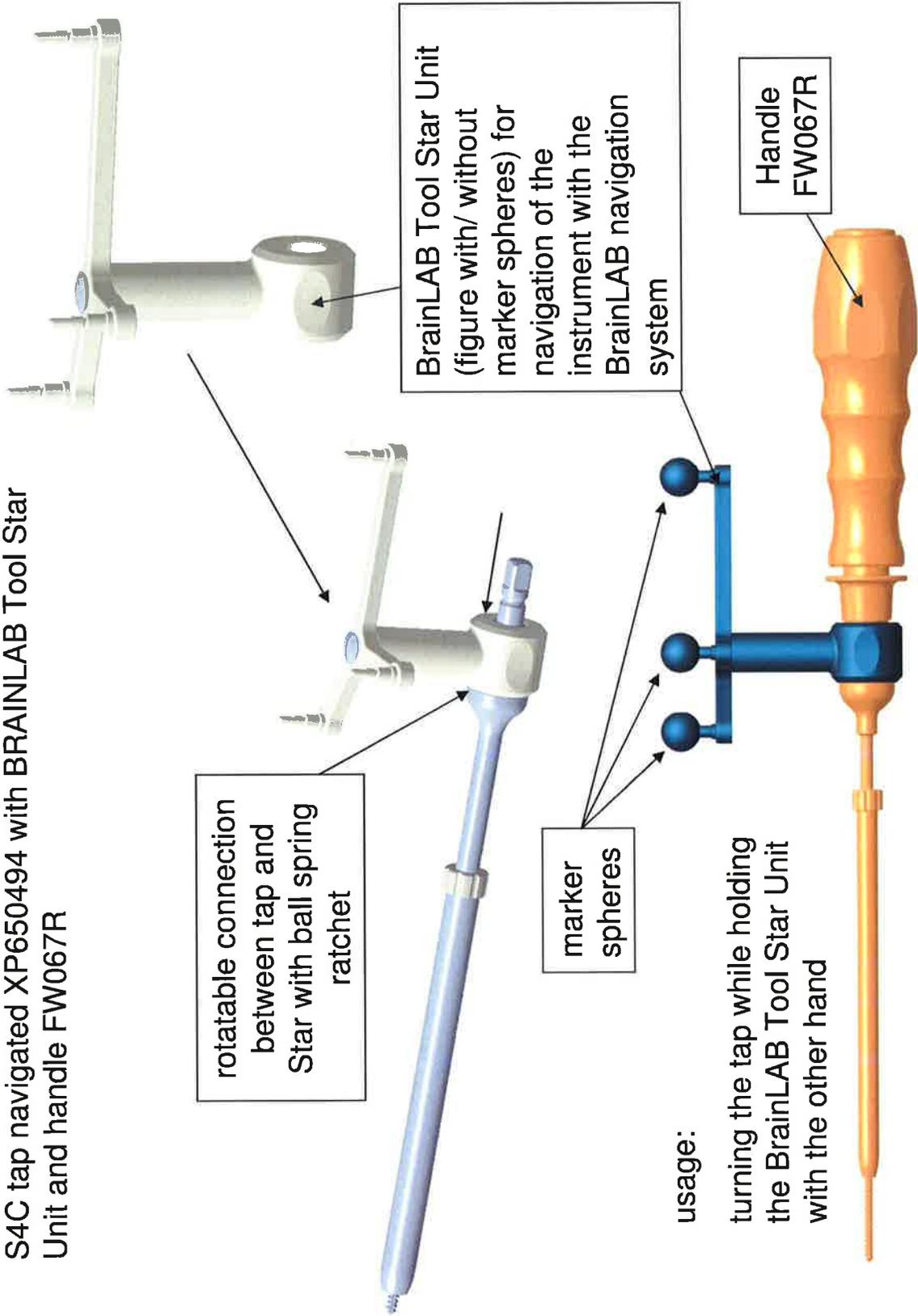


A pedicle probe (FW044R) can also be used to insure the integrity of the pedicle. The probe has a ball tip like the depth gauge.

**DRAFT**

**DRAFT**

**S4C tap navigated XP650494 with BRAINLAB Tool Star Unit and handle FW067R**



**DRAFT**

# Pedicle Screw Hole Preparation

S4C tap navigated XP650494



The tap is navigated, for tapping the hole for the 3,5mm screw (position and angle).

The next step is to tap the pre-drilled hole. Although the screws are equipped with a self-cutting tip, to ensure optimal bone purchase of the screws, tapping is recommended. The tap does not need to be inserted through the drill sleeve. Each tap is equipped with a self-retracting sleeve which prevents the risk of damaging surrounding tissue during tapping. For the 3.5mm mini-polyaxial screw, the 3.5mm tap navigated (XP650494) could be used. For the 4.0mm mini-polyaxial screw, the 4.0mm tap (FW047R) without navigation is selected. The taps are color coded as for the drills for simplification to match the screw body color, i.e. the 4mm tap has a purple titanium marking ring for identification. The appropriate tap is inserted manually into the pre-drilled hole while maintaining the appropriate trajectory. In the same manner, the remaining holes are drilled and tapped. The handle (FW067R) has a quick release coupling and is attached to the 1/4" square connector on the tap.

# Polyaxial Screw Insertion

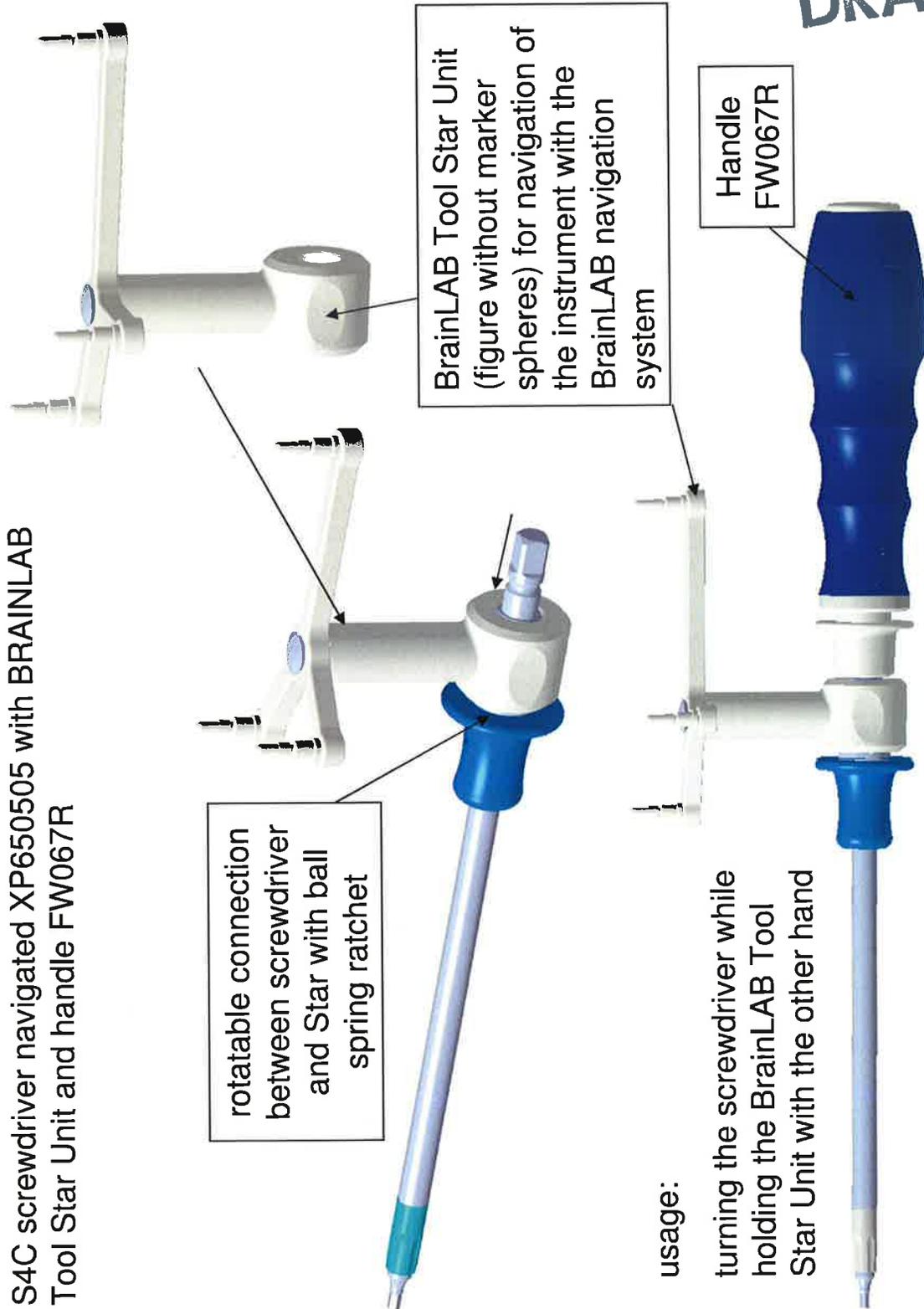
With the pedicles prepared and the proper screw length determined, the appropriate polyaxial screws are inserted into the pedicles bilaterally, using the self-holding polyaxial screwdriver (XP650505). The hex end of the polyaxial screwdriver must be fully engaged into the spherical head of the screw and the self-holding tip, then engaged by rotating the knob directly under the handle.

As for the taps, the screwdriver has a 1/4" square drive for attaching to the quick release coupling of the handle (FW067R).



**DRAFT**

**S4C screwdriver navigated XP650505 with BRAINLAB Tool Star Unit and handle FW067R**



usage:  
turning the screwdriver while  
holding the BrainLAB Tool  
Star Unit with the other hand

**SECTION VI  
STERILIZATION INFORMATION**

**STERILIZATION**

## VI. STERILIZATION

### A. Non-Sterile Device Information

Non-sterile instruments are packaged in a clear PE pouch with the appropriate labels attached. The overkill method with a half cycle is used to validate the steam sterilization according to 17665 part 1. The S4C Navigation Instruments are provided non sterile and may be sterilized using the chart below. Sterilization may be accomplished by steam autoclave (moist heat) in a standard pre-vacuum cycle. To achieve a sterility assurance level of  $10^{-6}$ , Aesculap recommends the following parameters:

Sterilization Method	Temperature	Minimum exposure time	
		Full Cycle Time Sterile Container System (perforated bottom)	Minimum Dry Time
Pre-vacuum	270° F - 275° F	4minutes	20 minutes

The above parameters have been validated for sterility in an Aesculap STERILCONTAINER System cleared by FDA for the sterilization and storage of these instruments.

Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle, design, and packaging / containerization. The manufacturer's instructions must be followed for each sterilization chamber.

Sterilization information can also be found in the Instruction for Use.

**SECTION VII  
BIOCOMPATIBILITY INFORMATION**

## VII. BIOCOMPATIBILITY INFORMATION

### Materials/ Biocompatibility

(b) (4)



**SECTION VIII**  
**Risk Analysis**

The risk analysis has been completed by BrainLab and conforms with ISO 14971.































**SECTION IX  
PERFORMANCE DATA**

## VIII. PERFORMANCE DATA

### Validation (Integration) Testing

(b)(4) Third Party Test Data





























































































































































































**APPENDIX B  
PREDICATE DEVICE INFORMATION**

K070106

APR 23 2007

## 510 (k) Summary of Safety and Effectiveness for VectorVision fluoro 3D

**Manufacturer:**

Address: BrainLAB AG  
Kapellenstrasse 12  
85622 Feldkirchen  
Germany  
Phone: +49 89 99 15 68 0  
Fax: +49 89 99 15 68 33

Contact Person: Mr. Per Persson

Summary Date: April 18, 2007

**Device Name:**

Trade name: VectorVision fluoro 3D  
Common/Classification Name: BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

**Predicate Device:**

VectorVision fluoro 3D (K024192)  
VectorVision spine (K053159).

Device Classification Name: Instrument, Stereotaxic  
Regulatory Class: Class II

**Intended Use:**

BrainLAB VectorVision fluoro3D is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or Intraoperative 2D or 3D image data.

VectorVision fluoro3D enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system.

The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

**Device Description:**

VectorVision fluoro 3D is a device that allows surgical planning and navigation. It links a surgical instrument, (tracked by passive marker sensor system) to a location on a virtual computer image, which is either based on patient's intraoperative 3D information acquired with a 3D C-arm or based on patient's intraoperative acquired 2D fluoro image(s) of an analog or digital c-arm.

The device enables the navigation based on 3D data and / or based on acquired fluoro images.

Based on 2D fluoro images, the registration is done automatically by using the exact spatial position information of the intra-operatively acquired fluoro images.

Based on 3D data, the registration is also done automatically by using the exact spatial position information of the start position of the scan. Beforehand, the 3D Siemens C-arm has to be calibrated in combination with the navigation system.

For 3D data, the paired point matching and the 2D 3D fluoro matching are also available as reregistration methods.

The last registration method uses two fluoro images (one in AP and one in lateral position) to regain accuracy on previously acquired 3D scans. This may become necessary if the reference on the patients bone has become lose.

The device assists the surgeon in performing certain surgical procedures as described in the indications for use.

**Substantial equivalence:**

VectorVision fluoro 3D has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB VectorVision fluoro 3D version 1.0 (K024192) and BrainLAB VectorVision spine version 5.5.1 (K053159).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 23 2007

BrainLAB AG  
% Mr. Per Persson  
Manager Regulatory Affairs  
Kapellenstraße 12  
85622 Feldkirchen  
Germany

Re: K070106  
Trade/Device Name: Vector Vision fluoro 3D  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic instrument  
Regulatory Class: II  
Product Code: HAW  
Dated: January 3, 2007  
Received: February 5, 2007

Dear Mr. Persson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

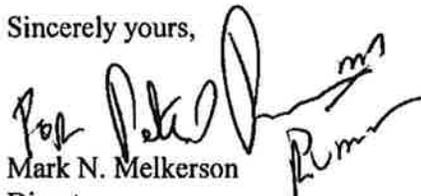
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Per Persson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070106

Device Name: Vector Vision fluoro 3D

### Indications For Use:

BrainLAB VectorVision fluoro3D is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or Intraoperative 2D or 3D image data.

VectorVision fluoro3D enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system.

The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

510(k) Number \_\_\_\_\_

  K070106

K130887/S1

FDA CDRH DMC  
JUN 14 2013  
Received

June 13, 2013

Mr. Michael Janda  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Springs, MD 20993-0002

Re: K130887 – S4C Navigation Instruments

Dear Mr. Janda,

Below please find the missing information that FDA has requested via e-mail per the Refuse to Accept Checklist received on 04/10/2013. An electronic copy of this response is provided for your convenience. The eCopy is an exact duplicate of the paper copy.

**A. Administrative:**

**4 (a)** - Predicate K070106 was chosen because it supports both of BrainLab's pre-calibrated and manual-calibrated instruments. K042721 was the first application supporting the use of pre-calibrated instruments. However, all other supported software applications listed below also support the use of pre-calibrated and manual-calibrated instruments based on the same software framework and file format.

Aesculap S4C instruments are integrated into the following current Brainlab Spine & Trauma navigation software applications:

- VectorVision Spine (version 5.5 and 5.6) – K053159
- Kolibri Spine (version 2.0) – K042721
- Trauma (version 2.6) – K062358
- VectorVision Fluoro3D (version 1.6 and 2.0) – K070106
- Spine & Trauma iCT (version 1.0) – K083310
- BrainLab Trauma (version 3.0) - 1100204
- Spine & Trauma 3D (version 2.0) – K070106
- Spine & Trauma 2D / Fluro Express (version 3.1) K110204

The 510K) summary page has been updated to reflect this information. Please see Attachment A.

30

## B. Device Description

**10 (a & b)** – The predicate implant systems that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152,

and K062327). There are no device-specific guidance or special controls that apply. All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

**11 (a, b)** – The S4C Spinal System is an implant system used to facilitate the biological process of spinal fusion. The system includes pedicle screws of various lengths, designs and two diameters (3.5 and 4.0mm) as well as 3.5mm rods of various lengths, cross connector clamps and hooks. The S4C pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The S4C 3.5 & 4.0mm polyaxial screws will be used with BrainLab's software for spinal application when being placed in the thoracic spine (T1-T3).

BrainLab's spine software applications are intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data. The spine software application enables computer assisted navigation of medical image data, which can either acquired preoperatively or intra-operatively by an appropriate image acquisition system. BrainLab's spine software system offers various screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

BrainLab's Indications do not have any restrictions on where it can be used in the spine. The indications for BrainLab's software applications are as follows: *The software offers screw implant size planning and navigation on rigid bone structures with pre-calibrated and additional individually-calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.*

**11 (c)** – Clearance is being requested for the instruments being listed on page 12 and 13 of the subject submission. These instruments are compatible with the 3.5 & 4.0mm polyaxial screws and will be used for pedicle preparation for screw placement (T1-T3) when used with BrainLab's Navigation Systems for spine applications.

**13 (a)** – Please see Attachment B for the product clearance table. The Aesculap S4C screws and instruments are not marketed with BrainLab's Navigation system. The screws and instruments are sold separately.

**13 (b)** – The Aesculap S4C Spinal System is a posterior spinal fixation systems used to facilitate the biological process of spinal fusion. The system is intended to promote fusion of the cervical and thoracic spine (C1-T3). The system consists of bone screws, rods, and connectors. The components are available in a variety of lengths in order to accommodate patient anatomy. The system is manufactured from Titanium/ Titanium Alloy and is provided nonsterile.

When intended to promote fusion of the cervical spine and thoracic spine (C1-T3) and is intended for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of the polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be placed in the cervical spine.

Please see Attachment C for a picture of the system.

**13 (c)** – Please see Attachment B for the product clearance table.

### **C. Substantial Equivalence Discussion**

**14 (b)** – Aesculap S4C instruments are integrated into the following current Brainlab Spine & Trauma navigation software applications:

- VectorVision Spine (version 5.5 and 5.6) – K053159
- Kolibri Spine (version 2.0) – K042721
- Trauma (version 2.6) – K062358
- VectorVision Fluoro3D (version 1.6 and 2.0) – K070106
- Spine & Trauma iCT (version 1.0) – K083310
- BrainLab Trauma (version 3.0) - 1100204
- Spine & Trauma 3D (version 2.0) – K070106
- Spine & Trauma 2D / Fluoro Express (version 3.1) K110204

The predicate implant system that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). This information has been updated on the 510(K) Summary Page in Attachment A.

**D. Proposed Labeling**

**17 (a,b)** – The warnings and precautions of the surgical technique and the packaging insert have been modified to match the Indications for Use form and the 510(k) Summary. Please be aware that the warning and precautions for the cleaning/disinfection and sterilization of the instruments has not been added to the surgical technique. A reference to the packaging insert has been included in the second page of the surgical technique.

Please see Attachment D for a copy of all updated labeling.

**20 (a, b, & c)** -- The predicate implant system that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). There are no device-specific guidance or special controls that apply. All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

**E. Sterilization –**

**22 (a)** – The FW662SU drill bit is an Aesculap product and is provided sterile for single use only. The disposable reflective marker spheres are provided sterile to the customer by BrainLab and have been cleared under K100038. BrainLab is responsible for this sterile product. It is not part of the Aesculap submission.

**22 (b)** – All other instruments (see chart below) are provided non-sterile. The instruments are re-usable. Sterilization may be accomplished by steam autoclave (moist heat) in a standard pre-vacuum cycle. The overkill method with a half cycle is used to validate the steam sterilization according to ISP 14655-Part 1. (This information can be found in Section VI – Sterilization – pg. 82).

**22 (c)** – The instruments listed in the chart below are reuseable. The validated cleaning & disinfections instructions for the instruments can be found starting on page 62 of the subject submission.

Reuseable Navigation Instruments	
Part#	Description
FW652R	Aesculap Star Unit Navigation Attachment
FW 653R	Cortical Punch for Navigated Drill Guide FW654R
FW654R	Navigated Drill Guide D3.5mm, Short
FW655R	Navigated Screw Tap, D3.5mm
FW656R	Navigated Screw Driver for Polyaxial Screws
FW657R	Reducing Sleeve D13mm for Calibration Tool

FW658R	Navigation Guide Sleeve D4.0mm – Smooth Shank
FW660R	Navigated Guide Sleeve D3.5 / 4.0mm
FJ985R	Apfelbaum Inner Sleeve Guide D4.0mm
FW661R	S4C Inner Sleeve Guide D3.5mm
FW663R	S4C Screw Tap 3.5mm

**23(b, c & d)** – The method used for gamma radiation was performed in accordance with ISO 11137- part 2 – method 1 which is used to establish the sterilization dose. The verification dose based on the bioburden was 4.0 kGy, and the effective sterilization dose (related to SAL  $10^{-6}$ ) was 15.8 kGy. This ensures that the regular minimum sterilization dose of the 25 kGy is effective.

The sterile instrument (FW662SU) is packaged in a double peelable thermoformed package. The upper and lower film is made from PA/EVOH/PE. Inside the primary package the implants are fixed through evacuation. The storage packaging is a folded cardboard box. This is the same materials and process used to package other sterile Aesculap products. A copy of the validation plan can be found in Attachment E.

#### F. Shelf Life

**26** – For FW662SU, the shelf life for the product is 5 years. The disposable reflective marker spheres are provided sterile to the customer by BrainLab and have been cleared under K100038. BrainLab is responsible for this sterile product. It is not part of the Aesculap submission.

**27** – A copy of the packaging validation report can be found in Attachment E.

**28** – The instruments are made out of the same materials (titanium alloy, stainless steel and PEEK). These materials have been accepted in previously cleared Aesculap orthopedic and spinal devices / instruments such as the S4C Spinal System (K050979). The material is not expected to degrade or change because of aging or storage conditions

#### H. Software

**32** – BrainLab has indicated that the level of concern for the software is moderate. The addition of the Aesculap instrumentation to BrainLab's spine software application does not compromise or change the performance or technology of the software application. Aesculap's submission introduces instrument with geometries, shapes and sizes that are compatible with existing spine applications cleared under BrainLab's various Navigation System submissions.

**33** – There is no software version specifically compatible as explained in detail below: BrainLab existing Spine & Trauma software applications support use of pre-calibrated and manual-calibrated instruments. Corresponding pre-calibrated instruments file format and software framework were released with corresponding software applications.

The dimensions and representations of pre-calibrated instruments are stored on instrument specific description files (based on the Brainlab navigation software file format and framework) that can be loaded and integrated into the existing Brainlab Navigation Software without changing the software itself. Information stored in instrument specific files are only read by software upon start.

Software integration tests have been done to verify that dimensions and information of pre-calibrated instruments are correctly stored in instrument specific description files, and that instruments are correctly displayed in software and can be used in combination with Brainlab software same as predicate Brainlab instruments.

The dimensions of manual-calibrated instruments are acquired by the Brainlab navigation software through a calibration procedure prior to each use, that is a basic functionality of the software, and instruments are shown with generic representations after calibration. For manual-calibrated instruments software integration tests were done, to verify that calibration of Aesculap instruments is possible in combination with Brainlab software application.

Further details about use of the precalibrated and manual-calibrated instruments is described in the SE Comparative Table provided by BrainLab in Section IV of the subject 510(K).

#### **J. Performance Data – General**

**37** – The predicate implant system that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). There are no device-specific guidance or special controls that apply. All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

If you have any questions or require additional information, please do not hesitate to contact me directly via phone at (610) 984-9274 or e-mail at [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com).

Sincerely,



Lisa M. Boyle  
Sr. Regulatory Affairs Specialist

enclosure

June 13, 2013

Mr. Michael Janda  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Springs, MD 20993-0002

Re: K130887 – S4C Navigation Instruments

Dear Mr. Janda,

Below please find the missing information that FDA has requested via e-mail per the Refuse to Accept Checklist received on 04/10/2013. An electronic copy of this response is provided for your convenience. The eCopy is an exact duplicate of the paper copy.

**A. Administrative:**

**4 (a)** - Predicate K070106 was chosen because it supports both of BrainLab's pre-calibrated and manual-calibrated instruments. K042721 was the first application supporting the use of pre-calibrated instruments. However, all other supported software applications listed below also support the use of pre-calibrated and manual-calibrated instruments based on the same software framework and file format.

Aesculap S4C instruments are integrated into the following current Brainlab Spine & Trauma navigation software applications:

- VectorVision Spine (version 5.5 and 5.6) – K053159
- Kolibri Spine (version 2.0) – K042721
- Trauma (version 2.6) – K062358
- VectorVision Fluoro3D (version 1.6 and 2.0) – K070106
- Spine & Trauma iCT (version 1.0) – K083310
- BrainLab Trauma (version 3.0) - 1100204
- Spine & Trauma 3D (version 2.0) – K070106
- Spine & Trauma 2D / Fluro Express (version 3.1) K110204

The 510K) summary page has been updated to reflect this information. Please see [Attachment A](#).

## B. Device Description

**10 (a & b)** – The predicate implant systems that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152,

and K062327). There are no device-specific guidance or special controls that apply. All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

**11 (a, b)** – The S4C Spinal System is an implant system used to facilitate the biological process of spinal fusion. The system includes pedicle screws of various lengths, designs and two diameters (3.5 and 4.0mm) as well as 3.5mm rods of various lengths, cross connector clamps and hooks. The S4C pedicle screws are limited to placement in T1-T3 in treating thoracic conditions only. The S4C 3.5 & 4.0mm polyaxial screws will be used with BrainLab's software for spinal application when being placed in the thoracic spine (T1-T3).

BrainLab's spine software applications are intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or intraoperative 2D or 3D image data. The spine software application enables computer assisted navigation of medical image data, which can either acquired preoperatively or intra-operatively by an appropriate image acquisition system. BrainLab's spine software system offers various screw implant size planning an navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools.

BrainLab's Indications do not have any restrictions on where it can be used in the spine. The indications for BrainLab's software applications are as follows: *The software offers screw implant size planning and navigation on rigid bone structures with pre-calibrated and additional individually-calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.*

**11 (c)** – Clearance is being requested for the instruments being listed on page 12 and 13 of the subject submission. These instruments are compatible with the 3.5 & 4.0mm polyaxial screws and will be used for pedicle preparation for screw placement (T1-T3) when used with BrainLab's Navigation Systems for spine applications.

**13 (a)** – Please see Attachment B for the product clearance table. The Aesculap S4C screws and instruments are not marketed with BrainLab's Navigation system. The screws and instruments are sold separately.

**13 (b)** – The Aesculap S4C Spinal System is a posterior spinal fixation systems used to facilitate the biological process of spinal fusion. The system is intended to promote fusion of the cervical and thoracic spine (C1-T3). The system consists of bone screws, rods, and connectors. The components are available in a variety of lengths in order to accommodate patient anatomy. The system is manufactured from Titanium/ Titanium Alloy and is provided nonsterile.

When intended to promote fusion of the cervical spine and thoracic spine (C1-T3) and is intended for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Failed previous fusion
- Tumors

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation r trauma in the cervical/upper thoracic (C1-T3) spine.

The use of the polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be place in the cervical spine.

Please see Attachment C for a picture of the system.

**13 (c)** – Please see Attachment B for the product clearance table.

### **C. Substantial Equivalence Discussion**

**14 (b)** – Aesculap S4C instruments are integrated into the following current Brainlab Spine & Trauma navigation software applications:

- VectorVision Spine (version 5.5 and 5.6) – K053159
- Kolibri Spine (version 2.0) – K042721
- Trauma (version 2.6) – K062358
- VectorVision Fluoro3D (version 1.6 and 2.0) – K070106
- Spine & Trauma iCT (version 1.0) – K083310
- BrainLab Trauma (version 3.0) - 1100204
- Spine & Trauma 3D (version 2.0) – K070106
- Spine & Trauma 2D / Fluro Express (version 3.1) K110204

The predicate implant system that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). This information has been updated on the 510(K) Summary Page in Attachment A.

**D. Proposed Labeling**

**17 (a,b)** – The warnings and precautions of the surgical technique and the packaging insert have been modified to match the Indications for Use form and the 510(k) Summary. Please be aware that the warning and precautions for the cleaning/disinfection and sterilization of the instruments has not been added to the surgical technique. A reference to the packaging insert has been included in the second page of the surgical technique.

Please see Attachment D for a copy of all updated labeling.

**20 (a, b, & c)** – The predicate implant system that will be used with BrainLab's Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). There are no device-specific guidance or special controls that apply. All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where applicable.

**E. Sterilization –**

**22 (a)** – The FW662SU drill bit is an Aesculap product and is provided sterile for single use only. The disposable reflective marker spheres are provided sterile to the customer by BrainLab and have been cleared under K100038. BrainLab is responsible for this sterile product. It is not part of the Aesculap submission.

**22 (b)** – All other instruments (see chart below) are provided non-sterile. The instruments are re-usable. Sterilization may be accomplished by steam autoclave (moist heat) in a standard pre-vacuum cycle. The overkill method with a half cycle is used to validate the steam sterilization according to ISP 14655-Part 1. (This information can be found in Section VI – Sterilization – pg. 82).

**22 (c)** – The instruments listed in the chart below are reuseable. The validated cleaning & disinfections instructions for the instruments can be found starting on page 62 of the subject submission.

Reuseable Navigation Instruments	
Part#	Description
FW652R	Aesculap Star Unit Navigation Attachment
FW 653R	Cortical Punch for Navigated Drill Guide FW654R
FW654R	Navigated Drill Guide D3.5mm, Short
FW655R	Navigated Screw Tap, D3.5mm
FW656R	Navigated Screw Driver for Polyaxial Screws
FW657R	Reducing Sleeve D13mm for Calibration Tool

FW658R	Navigation Guide Sleeve D4.0mm – Smooth Shank
FW660R	Navigated Guide Sleeve D3.5 / 4.0mm
FJ985R	Apfelbaum Inner Sleeve Guide D4.0mm
FW661R	S4C Inner Sleeve Guide D3.5mm
FW663R	S4C Screw Tap 3.5mm

**23(b, c & d)** – The method used for gamma radiation was performed in accordance with ISO 11137- part 2 – method 1 which is used to establish the sterilization dose. The verification dose based on the bioburden was 4.0 kGy, and the effective sterilization dose (related to SAL  $10^{-6}$ ) was 15.8 kGy. This ensures that the regular minimum sterilization dose of the 25 kGy is effective.

The sterile instrument (FW662SU) is packaged in a double peelable thermoformed package. The upper and lower film is made from PA/EVOH/PE. Inside the primary package the implants are fixed through evacuation. The storage packaging is a folded cardboard box. This is the same materials and process used to package other sterile Aesculap products. A copy of the validation plan can be found in Attachment E.

#### F. Shelf Life

**26** – For FW662SU, the shelf life for the product is 5 years. The disposable reflective marker spheres are provided sterile to the customer by BrainLab and have been cleared under K100038. BrainLab is responsible for this sterile product. It is not part of the Aesculap submission.

**27** – A copy of the packaging validation report can be found in Attachment E.

**28** – The instruments are made out of the same materials (titanium alloy, stainless steel and PEEK). These materials have been accepted in previously cleared Aesculap orthopedic and spinal devices / instruments such as the S4C Spinal System (K050979). The material is not expected to degrade or change because of aging or storage conditions

#### H. Software

**32** – BrainLab has indicated that the level of concern for the software is moderate. The addition of the Aesculap instrumentation to BrainLab’s spine software application does not compromise or change the performance or technology of the software application. Aesculap’s submission introduces instrument with geometries, shapes and sizes that are compatible with existing spine applications cleared under BrainLab’s various Navigation System submissions.

**33** – There is no software version specifically compatible as explained in detail below: Brainlab existing Spine & Trauma software applications support use of pre-calibrated and manual-calibrated instruments. Corresponding pre-calibrated instruments file format and software framework were released with corresponding software applications.

The dimensions and representations of pre-calibrated instruments are stored on instrument specific description files (based on the Brainlab navigation software file format and framework) that can be loaded and integrated into the existing Brainlab Navigation Software without changing the software itself. Information stored in instrument specific files are only read by software upon start.

Software integration tests have been done to verify that dimensions and information of pre-calibrated instruments are correctly stored in instrument specific description files, and that instruments are correctly displayed in software and can be used in combination with Brainlab software same as predicate Brainlab instruments.

The dimensions of manual-calibrated instruments are acquired by the Brainlab navigation software through a calibration procedure prior to each use, that is a basic functionality of the software, and instruments are shown with generic representations after calibration. For manual-calibrated instruments software integration tests were done, to verify that calibration of Aesculap instruments is possible in combination with Brainlab software application.

Further details about use of the precalibrated and manual-calibrated instruments is described in the SE Comparative Table provided by BrainLab in Section IV of the subject 510(K).

#### **J. Performance Data – General**

37 – The predicate implant system that will be used with BrainLab’s Navigation System is the Aesculap S4C Spinal System (K050797, K060152, and K062327). There are no device-specific guidance or special controls that apply. All required testing per “Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements” were done where applicable. In addition, testing per the “Spinal System 510(k)s” was completed where applicable.

If you have any questions or require additional information, please do not hesitate to contact me directly via phone at (610) 984-9274 or e-mail at [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com).

Sincerely,



Lisa M. Boyle  
Sr. Regulatory Affairs Specialist

enclosure

# **ATTACHMENT A**

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Aesculap® Implant Systems (AIS) S4 Spinal System**  
June 10, 2013

**COMPANY:** Aesculap® Implant Systems (AIS), LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle, Sr Regulatory Affairs Specialist  
610-984-9274 (phone)  
610-791-6882 (fax)  
[lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**TRADE NAME:** AIS S4 Cervical Navigation Instruments  
**COMMON NAME:** Stereotaxic Instrument

**REGULATION NUMBER:** 882.4560 – Instrument, Stereotaxic

**PRODUCT CODE:** OLO and HAW  
**REVIEW PANEL:** Orthopedics

**INDICATIONS FOR USE**

The AIS S4 Cervical Navigation Instruments are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. They are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

**DEVICE DESCRIPTION**

The AIS S4 Cervical Navigation Instruments are manual surgical instruments which are designed to interface with BrainLAB's already cleared surgical navigation systems. Instruments in this system may be pre-calibrated or manually calibrated to already cleared systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general or manual functions within the orthopedic surgical environment.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The AIS S4 Cervical Navigation Instruments have similar design features, materials, and indications for use as the current AIS manual instruments (class I instrumentation) and are substantially equivalent to the instruments used with the BrainLAB's various navigation systems.

### **PERFORMANCE DATA**

BrainLAB conducted validation activities including usability testing with the AIS Navigation Instruments. The AIS Navigation Instruments met the performance requirements. No safety or effectiveness issues were raised by the performance testing. Clinical data was not needed for the AIS Navigation Instruments.

### **PREDICATE DEVICES**

- VectorVision Spine – K053159
- Kolibri Spine – K042721
- Trauma – K062358
- VectorVision Fluoro3D – K070106
- Spine & Trauma iCT – K083310
- BrainLab Trauma - 1100204
- Spine & Trauma 3D – K070106
- Spine & Trauma 2D / Fluro Express – K110204

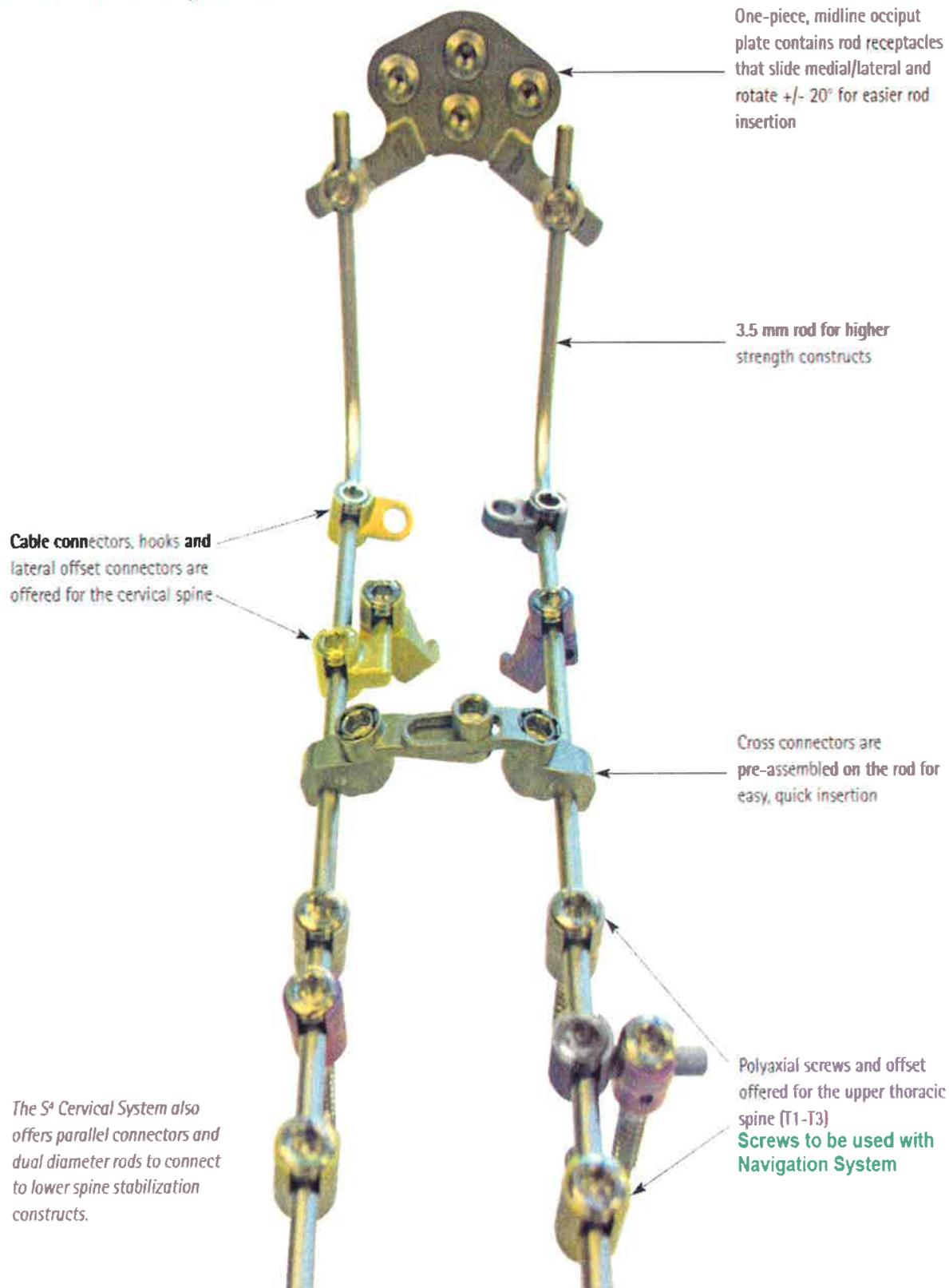
## **ATTACHMENT B**

<b>S4C Implants to be used with BrainLab's Navigation Systems</b>		
<b>Part Number</b>	<b>Description</b>	<b>510(k)</b>
SW161T OR SX460T	S4C POLYAXIAL SCREW 3.5 X 10 MM	K060152
SW162T OR SX462T	S4C POLYAXIAL SCREW 3.5 X 12 MM	K050979
SW 163T OR SX464T	S4C POLYAXIAL SCREW 3.5 X 14 MM	K050979
SW 164T OR SX466T	S4C POLYAXIAL SCREW 3.5 X 16 MM	K050979
SW165T OR SX468T	S4C POLYAXIAL SCREW 3.5 X 18 MM	K050979
SW166T OR SX470T	S4C POLYAXIAL SCREW 3.5 X 20 MM	K050979
SW167T OR SX472T	S4C POLYAXIAL SCREW 3.5 X 22 MM	K060152
SW168T OR SX474T	S4C POLYAXIAL SCREW 3.5 X 24 MM	K050979
SW169T OR SX476T	S4C POLYAXIAL SCREW 3.5 X 26 MM	K050979
SW170T OR SX478T	S4C POLYAXIAL SCREW 3.5 X 28 MM	K050979
SW171T OR SX480T	S4C POLYAXIAL SCREW 3.5 X 30 MM	K050979
SW182T OR SX461T	S4C POLYAXIAL SCREW 4.0 X 10 MM	K050979
SW172T OR SX463T	S4C POLYAXIAL SCREW 4.0 X 12 MM	K060152
SW173T OR SX465T	S4C POLYAXIAL SCREW 4.0 X 14 MM	K050979
SW174T OR SX467T	S4C POLYAXIAL SCREW 4.0 X 16 MM	K050979
SW175T OR SX469T	S4C POLYAXIAL SCREW 4.0 X 18 MM	K050979
SW176T OR SX471T	S4C POLYAXIAL SCREW 4.0 X 20 MM	K050979
SW177T OR SX473T	S4C POLYAXIAL SCREW 4.0 X 22 MM	K050979
SW178T OR SX475T	S4C POLYAXIAL SCREW 4.0 X 24 MM	K060152
SW179T OR SX477T	S4C POLYAXIAL SCREW 4.0 X 26 MM	K050979
SW180T OR SX479T	S4C POLYAXIAL SCREW 4.0 X 28 MM	K050979
SW181T OR SX481T	S4C POLYAXIAL SCREW 4.0 X 30 MM	K050979
SW141T OR SX410T	S4C FAVOURED ANGLE SCREW 4.0 X 10 MM	K050979
SW142T OR SX412T	S4C FAVOURED ANGLE SCREW 4.0 X 12 MM	K050979
SW143T OR SX414T	S4C FAVOURED ANGLE SCREW 4.0 X 14 MM	K050979
SW144T OR SX416T	S4C FAVOURED ANGLE SCREW 4.0 X 16 MM	K050979
SW145T OR SX418T	S4C FAVOURED ANGLE SCREW 4.0 X 18 MM	K050979
SW146T OR SX420T	S4C FAVOURED ANGLE SCREW 4.0 X 20 MM	K050979
SW147T OR SX422T	S4C FAVOURED ANGLE SCREW 4.0 X 22 MM	K050979
SW148T OR SX424T	S4C FAVOURED ANGLE SCREW 4.0 X 24 MM	K050979
SW149T OR SX426T	S4C FAVOURED ANGLE SCREW 4.0 X 26 MM	K060152
SW150T OR SX428T	S4C FAVOURED ANGLE SCREW 4.0 X 28 MM	K050979
SW151T OR SX430T	S4C FAVOURED ANGLE SCREW 4.0 X 30 MM	K050979
SW152T OR SX432T	S4C FAVOURED ANGLE SCREW 4.0 X 32 MM	K050979
SW153T OR SX434T	S4C FAVOURED ANGLE SCREW 4.0 X 34 MM	K050979
SW154T OR SX436T	S4C FAVOURED ANGLE SCREW 4.0 X 36 MM	K050979
SW155T OR SX438T	S4C FAVOURED ANGLE SCREW 4.0 X 38 MM	K050979
SW156T OR SX440T	S4C FAVOURED ANGLE SCREW 4.0 X 40 MM	K050979
SW157T OR SX442T	S4C FAVOURED ANGLE SCREW 4.0X42MM	K050979

SW158T OR SX444T	S4C FAVOURED ANGLE SCREW 4.0X44MM	K050979
SW159T OR SX446T	S4C FAVOURED ANGLE SCREW 4.0X46MM	K050979
SW160T OR SX448T	S4C FAVOURED ANGLE SCREW 4.0X48MM	K060152
SW121T OR SX450T	S4C FAVOURED ANGLE SCREW 4.0X50MM	K060152
SW122T OR SX452T	S4C FAVOURED ANGLE SCREW 4.0X52MM	K060152
SW123T OR SX454T	S4C FAVOURED ANGLE SCREW 4.0X54MM	K060152
SW124T OR SX456T	S4C FAVOURED ANGLE SCREW 4.0X56MM	K060152

# **ATTACHMENT C**

## S<sup>4</sup> Cervical System



## **ATTACHMENT D**

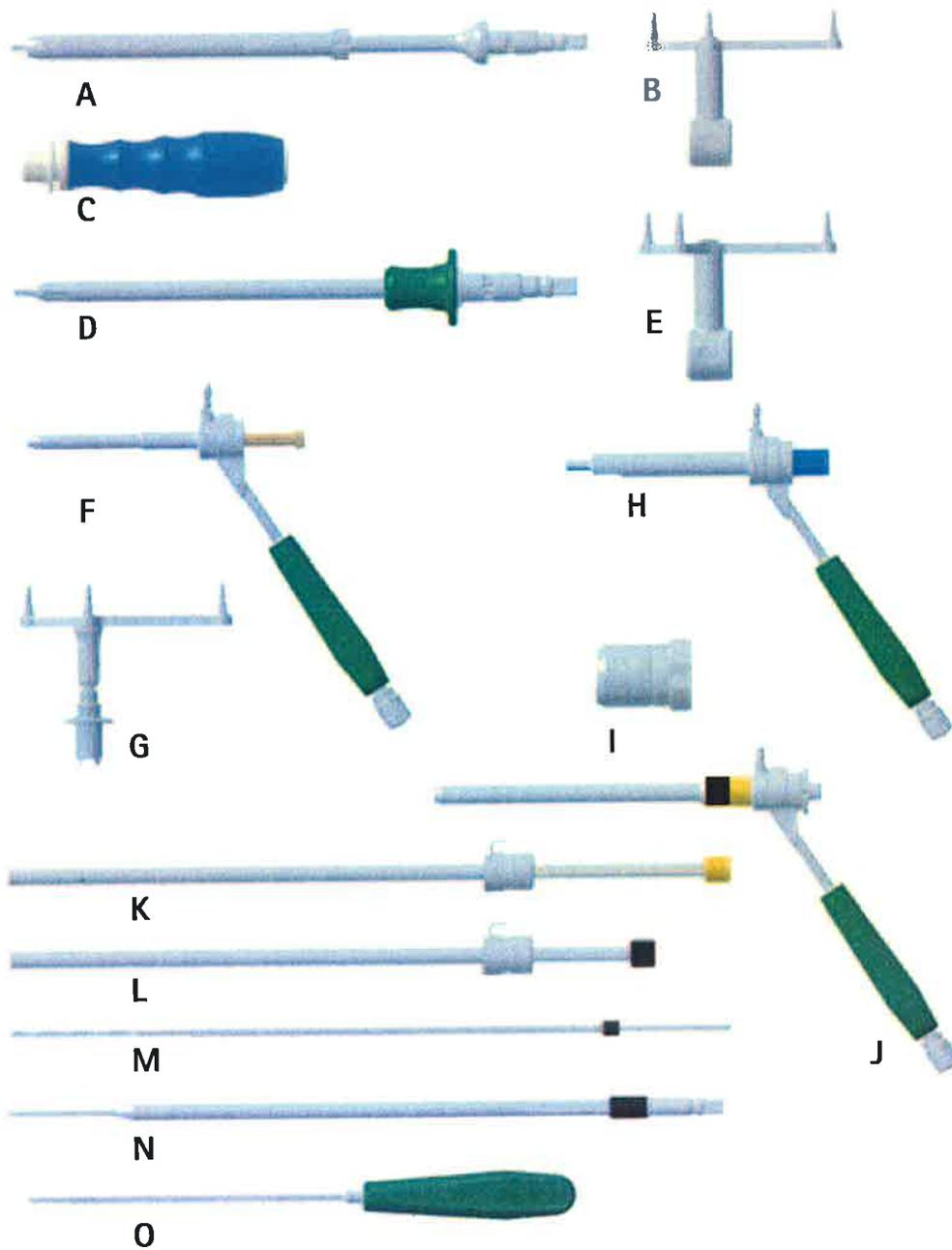
# Aesculap Spine

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- GB** Instructions for use/Technical description
- USA** S<sup>4</sup> Cervical - Navigated Instruments
- D** Gebrauchsanweisung/Technische Beschreibung  
S<sup>4</sup> Cervical - Navigierte Instrumente
- F** Mode d'emploi/Description technique  
S<sup>4</sup> Cervical - Instruments navigués
- E** Instrucciones de manejo/Descripción técnica  
S<sup>4</sup> Cervical Instrumental de navegación
- I** Istruzioni per l'uso/Descrizione tecnica  
S<sup>4</sup> Cervical - Strumenti navigati
- P** Instruções de utilização/Descrição técnica  
S<sup>4</sup> Cervical - Instrumentos de navegação
- NL** Gebruiksaanwijzing/Technische beschrijving  
S<sup>4</sup> Cervical - genavigeerde instrumenten
- DK** Brugsanvisning/Teknisk Beskrivelse  
S<sup>4</sup> Cervical - Navigerede instrumenter
- CZ** Návod k použití/Technický popis  
Navigované nástroje S<sup>4</sup> Cervical

**B | BRAUN**  
SHARING EXPERTISE



**S<sup>4</sup> Cervical - Navigated Instruments**

**Legend**

- A Navigated screw tap  $\varnothing$  3.5 mm (FW655R)
- B IGS Tool Star Unit (pre-calibrated) (Brainlab) (S5830-20A)
- C Handle (FW165R with ratchet or FW067R without ratchet)
- D Navigated screwdriver for polyaxial screw (FW656R)
- E IGS Tool Star Unit ML (calibration with ICM4) (Brainlab) (S5830-25A)
- F Navigated drill guide  $\varnothing$  3.5 mm, short (FW654R)
- G Aesculap star unit Navigation attachment (FW652R)
- H Navigated guide sleeve  $\varnothing$  4.0 mm for smooth-shank screws (FW658R)
- I Reduction sleeve  $\varnothing$  13 mm for Brainlab Instrument Calibration Matrix Rev. 4 (FW657R)
- J Navigated guide sleeve  $\varnothing$  3.5/4.0 mm (FW660R)
- K C1/C2 inner sleeve guide  $\varnothing$  4 mm (FJ985R)
- L C1/C2 inner sleeve guide  $\varnothing$  3.5 mm (FW661R)
- M C1/C2 drill bit  $\varnothing$  2.4 mm (FW662SU)
- N C1/C2 screw tap  $\varnothing$  3.5 mm (FW663R)
- O Cortical punch for navigated drill guide FW654R (FW653R)

**Symbols on product and packages**

Symbol	Explanation
	Sterilization using irradiation
	Not for reuse in intended applications as defined by the manufacturer
	Use by
	Caution, general warning symbol Caution, see documentation supplied with the product
	Date of manufacture

**Intended Use**

The S4C Navigation Instruments listed within are intended to assist the surgeon in locating anatomical structures in either open, minimally invasive, or percutaneous procedures. Indication and contraindications are specified in the instruction for use for implants (SOP-AIC-5000169)

The S4C Navigation Instruments are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

The instruments listed in the captions may only be used with the Brainlab navigation system. For safe handling prior to the operation, read Spine & Trauma user manual for Brainlab instruments and the corresponding software manual for the Brainlab spine application used.

**Combination specifications**

Aesculap and Brainlab accept absolutely no responsibility if instruments, awls or drills other than those named below are used with the corresponding drill guides and guide sleeves.

- Only combine S<sup>4</sup>C navigated drill guide F with:
  - S<sup>4</sup>C-cortical punch for S<sup>4</sup>C-drill guide  $\varnothing$
  - Standard drill bit,  $\varnothing$  2.4 mm for  $\varnothing$  3.5 mm screws (FW051SU)
- Only combine S<sup>4</sup>C navigated guide sleeve  $\varnothing$  4.0 mm H for smooth-shank screws with:
  - Smooth-shank screw bone awl (FW085R)
  - Smooth-shank screw drill (FW086SU)
  - Smooth-shank screw tap (FW087R)
  - Polyaxial screwdriver (FW070R)
  - Navigated screwdriver for polyaxial screw (FW656R)
  - Apfelbaum ball end screwdriver, short (FJ968R)
- Only combine S<sup>4</sup>C navigated guide sleeve  $\varnothing$  3.5/4.0 mm J with:
  - approved Apfelbaum C1/C2 obturator (FJ983R)
  - Apfelbaum trocar (FJ984R)
  - Favored Angle screw drill  $\varnothing$  2.9 mm for  $\varnothing$  4 mm screws (FW088SU)
  - Favored Angle screw tap  $\varnothing$  4 mm (FW089R)
  - C1/C2 inner sleeve guide  $\varnothing$  4 mm K (FJ985R)
  - S<sup>4</sup>C Favored Angle screwdriver (FW069R)
  - C1/C2 drill bit  $\varnothing$  2.4 mm for  $\varnothing$  3.5 mm screws (FW662SU) M
  - C1/C2 screw tap  $\varnothing$  3.5 mm (FW663R) N
  - C1/C2 inner sleeve guide  $\varnothing$  3.5 mm (FW661R) L
  - Apfelbaum ball end screwdriver (FJ988R)

**Note**

K-wires generally may not be used with the S<sup>4</sup>C system.

## Safe handling and preparation

### CAUTION

Federal law restricts this device to sale by or on order of a physician!



WARNING

**Risk of injury caused by incorrect operation of the product!**

- Attend appropriate product training before using the product.
- For information regarding such training, please contact your national B. Braun/Aesculap agency.

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, follow, and keep safe the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Remove the transport packaging and thoroughly clean the new product, either manually or mechanically, prior to its initial sterilization.
- Store any new or unused products in a dry, clean, and safe place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts.
- To avoid damage to the working end: Carefully insert the product through the working channel (e.g. trocar).

Ø S<sup>4</sup>C1/C2 drill bit 2.4 mm (FW662SU), standard drill Ø 2.4 mm (FW051SU), Favored Angle screw drill Ø 2.9 mm (FW088SU) and drill Ø 2.9 mm for smooth-shank screws (FW086SU)



DANGER

**Risk of infection of patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!**

- Do not reuse the product.

The product is gamma-sterilized and ships in sterile packaging. The product must not be reused.

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- Read, follow, and keep safe the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Do not use products from open or damaged sterile packaging.

- Prior to each use, inspect the product for loose, bent, broken, cracked or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Do not use the product after expiry of its use-by date.

## Safe operation



WARNING

**Risk of injury and/or malfunction!**

- Always carry out a function check prior to using the product.



WARNING

**Risk of injury to the patient!**

- Handle S<sup>4</sup>C instruments with the greatest of care as they are extremely precise and highly sensitive.
- Check accurate calibration of dropped or damaged S<sup>4</sup>C instruments, or send them to the Aesculap Technical Service.



WARNING

**Risk of injury to the patient!**

- Prior to the operation, plan the configuration of the operating room, the assembly of the instruments and the alignment of the reference star.
- Ensure that the navigation camera has an unrestricted view on the reflective marker spheres of the instruments.



WARNING

**Risk of injury to the patient!**

- Ensure that the instruments used are not bent or damaged.
- Before use, check the precision of the instruments, particularly that of fine instruments. For this, hold the instrument tip in the pivot point of the Brainlab Instrument Calibration Matrix Rev. 4.



WARNING

**Risk of injury to the patient!**

- Use navigated S<sup>4</sup>C instruments only with Brainlab disposable reflective marker spheres.

### Note

For further information on the correct handling of the marker spheres, see corresponding Brainlab user manual.

S<sup>4</sup> Cervical - Navigated InstrumentsPreparing holes for S<sup>4</sup>C screws with navigation**Risk of injury to the patient!**

- Observe the combination specifications

To center punch the screw holes in the cortical layer for the self-tapping S<sup>4</sup>C screws Ø 3.5 mm with navigation, use the S<sup>4</sup>C navigated drillguide Ø 3.5 mm F only together with S<sup>4</sup>C cortical punch for S<sup>4</sup>C navigated drill guide O.

To center punch screw holes in the cortical layer without navigation, see instructions for use S<sup>4</sup> Cervical Instruments (TA011984).

**Risk of damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue when inserting the cortical punch without drill guide!**

- Use the cortical punch only with drill guide FW654R.

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 of the Aesculap star unit G against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C drill guide F. When doing so, ensure that the pin of the adapter 3 engages in the recess on the star unit.
- Release locking sleeve 1.

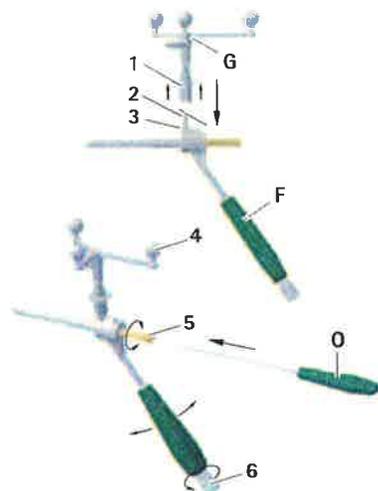


Fig. 1 Mounting the Aesculap star unit on S<sup>4</sup>C drill guide FW654R

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the cortical punch O for navigated drill guide is removed.
- To ensure the camera has an unrestricted view on the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the S<sup>4</sup>C drill guide F and turn the Aesculap star unit G to the desired position.
- Once the desired position is reached, tighten knob 6 again.
- Adjust the center punch depth by turning the depth stop 5 on the S<sup>4</sup>C drill guide F. The maximum depth is 6 mm.
- Insert S<sup>4</sup>C cortical punch O into S<sup>4</sup>C drill guide F.
- Check the pre-set center punch depth with a caliper (e.g. AA845R).
- To open the cortical bone, press S<sup>4</sup>C cortical punch to the preset depth under control with the Brainlab navigation system.

Drilling holes for the S<sup>4</sup>C screws**Risk of injury from an incorrectly placed hole or a hole that is too deep!**

- Do not sharpen the drill, as this would cause imprecise or incorrect readings on the depth gauge.
- Replace blunt drills with new ones.

The drill is applied with a S<sup>4</sup>C drill guide and drilled in either manually with the drill handle (FJ839R) or with a motor system with the Aesculap Intra-handpiece (e.g. GD450R/GD456R).

## Assembling the drill and drill handle (for manual drilling only)

**Risk of damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue through incorrect drilling!**

- Use only the correct S<sup>4</sup>C drill guides to drill holes. Insert drill only with the correct drill guide.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AA845R, Caspar instrument for anterior cervical fusion).



**DANGER**

**Injury to spinal cord and nerve roots caused by application of a drill that is too long!**

- Use the X-ray image to select an appropriate drill length prior to the operation.
- The drill may only be aligned and inserted under radiographic control and/or with the aid of a navigation system.
- Select a drill of a length equivalent to the intended drill hole depth.

- Insert drill in the drill handle (FJ839R), see Fig. 2.
- Retract and hold locking sleeve against the spring pressure in the direction of the arrow.
- Push the drill into the receptacle of the drill handle as far as it will go.
- Slightly rotate the drill and release locking sleeve. The drill engages audibly, see Fig. 2.

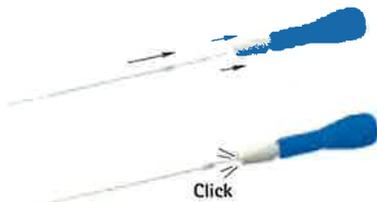


Fig. 2 Assembling the drill



**DANGER**

**Risk of injury and/or damage to the drill if the drill rotation speed is too high!**

- Use the lowest drilling speed possible, so that you can control the drilling depth.
- Do not bend the drill during the drilling process.

#### Drilling holes for S<sup>4</sup>C screws Ø 3.5 mm



**WARNING**

**Risk of injury to the patient!**

- Observe the combination specifications

For controlled drilling of the holes for S<sup>4</sup>C-screws Ø 3.5 mm with standard drill Ø 2.4 mm (FW051SU), the S<sup>4</sup>C navigated drill guide Ø 3.5 mm F (FW654R) must always be used.

#### Note

The drill Ø 2.9 mm (FW052SU) may not be used with S<sup>4</sup>C navigated drill guide F.

To drill the holes for the screws with Ø 4 mm, use standard drill guide FW053R without navigation, see instructions for use for S<sup>4</sup>C Cervical Instruments (TA011984).

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 of the Aesculap star unit G against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C drill guide F. When doing so, ensure that the pin of the adapter 3 engages in the recess on the star unit.
- Release locking sleeve 1.

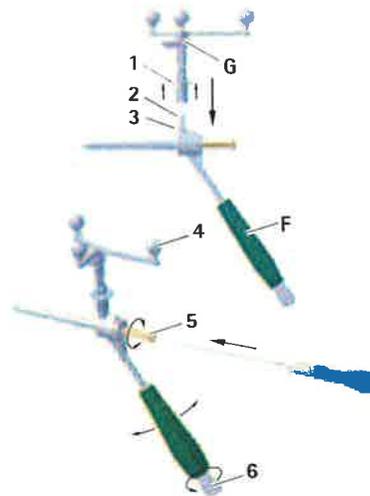


Fig. 3 Mounting the Aesculap star unit on S<sup>4</sup>C drill guide FW654R

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the drill FW051SU is removed.
- To ensure the camera has an unrestricted view on the reflective marker spheres, unscrew knob 6 on the handle of the S<sup>4</sup>C drill guide F and turn the Aesculap star unit G to the desired position, see Fig. 1.
- Once the desired position is reached, tighten knob 6 again.
- Adjust the drill depth by turning the depth stop 5 on the S<sup>4</sup>C drill guide F.
- Insert the drill with mounted handle or Intra-handpiece into S<sup>4</sup>C drill guide F.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AA845R, Caspar instrument for anterior cervical fusion).
- Drill to the pre-set depth under control with the Brainlab navigation system.

## S<sup>4</sup> Cervical - Navigated Instruments

### Tapping (optional)

S<sup>4</sup>C screws are self-tapping. However, if the bone quality is found to be hard during the operation, the surgeon can also pre-tap the thread with the S<sup>4</sup>C screw tap.

- For navigated tapping of the drill holes for screws Ø 3.5 mm, use S<sup>4</sup>C navigated screw tap **A**.
- For tapping the drill holes for screws Ø 4 mm, use the standard screw tap without navigation (FW047R), see TA011984.



**Risk of tissue injury when using the S<sup>4</sup>C screw tap (A) and damage to bone thread!**

- Prior to using the S<sup>4</sup>C screw tap, ensure that the moveable sleeve of the screw tap retracts correctly.

- Mount the Brainlab reflective marker spheres **4** onto the IGS Tool Star Unit **B** (pre-calibrated), see Brainlab user manual.
- Push the IGS Tool Star Unit onto the shaft **7** of the S<sup>4</sup>C navigated screw tap **A**. Ensure that the star unit is securely fitted onto the shaft of the S<sup>4</sup>C screw tap.

#### Note

The star unit can be rotated on the shaft of the S<sup>4</sup>C screw tap.

- Retract and hold locking sleeve **8** against the spring pressure.
  - Attach S<sup>4</sup>C handle (FW067R or FW165R) to S<sup>4</sup>C navigated screw tap **A**.
  - Push S<sup>4</sup>C handle onto the shaft of the S<sup>4</sup>C navigated screw tap **A**.
  - Release locking sleeve **8**, see Fig. 4.
- Check that the S<sup>4</sup>C handle is engaged.

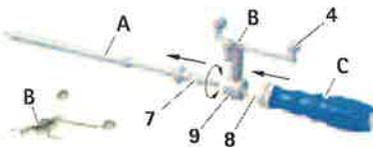


Fig. 4 Mounting the IGS Tool Star Unit and S<sup>4</sup>C handle onto the S<sup>4</sup>C screw tap



**Risk of injury to the patient!**

- Before use, ensure that the selected instrument has been correctly assembled.
- Ensure that the arrow on the underside of the IGS Tool Star Unit (pre-calibrated) is pointing to the tip of the tool.

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 5th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.

- To tap the thread, hold the IGS Tool Star Unit **B** at the planned indentations with one hand, and with the other hand screw in S<sup>4</sup>C handle **C** slowly and steadily under control with the Brainlab navigation system, until the required depth is reached.
- Use the scale behind the retractable sleeve of the S<sup>4</sup>C screw tap to read the depth during the tapping process, see Fig. 5.



Fig. 5 Screw tap with readable thread depth

### Positioning S<sup>4</sup>C screw under navigation and temporarily fixing it in place



**Risk of injury to the patient!**

- Use S<sup>4</sup>C screwdriver only with IGS Tool Star Unit **ML** for manual calibration.
- If you change screws, perform the calibration again.

- To position S<sup>4</sup>C screws Ø 3.5 mm and Ø 4 mm under navigation, use S<sup>4</sup>C navigated screwdriver **D**.
- Mount the Brainlab reflective marker spheres **4** onto IGS Tool Star Unit **ML E**, see Brainlab user manual.
- Push the IGS Tool Star Unit **ML E** onto the shaft **10** of the S<sup>4</sup>C screwdriver **D**. Ensure that the star unit is securely fitted onto the shaft of the S<sup>4</sup>C screwdriver.

#### Note

The star unit can be rotated on the shaft of the S<sup>4</sup>C screwdriver.

- Retract and hold locking sleeve **8** against the spring pressure.
  - Mount S<sup>4</sup>C handle (FW067R or FW165R) onto S<sup>4</sup>C screwdriver **D**.
  - Push S<sup>4</sup>C handle onto the shaft of S<sup>4</sup>C screwdriver **D**.
  - Release locking sleeve **8**, see Fig. 6.
- Check that the S<sup>4</sup>C handle is engaged.

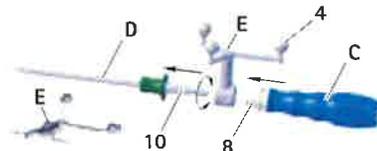


Fig. 6 Mounting the IGS Tool Star Unit and S<sup>4</sup>C handle (FW067R or FW165R) onto the S<sup>4</sup>C screwdriver



**Note**

The S<sup>4</sup>C screwdriver is fitted with a self-retaining function to prevent the S<sup>4</sup>C screw from falling off when it is passed to the surgeon.

- Retract and hold holding sleeve 12 on the S<sup>4</sup>C screwdriver D.
- Insert the tip of the S<sup>4</sup>C screwdriver D fully into the hexagon of the screw 11.
- Release holding sleeve 12.  
Ensure that the screw 11 is securely in place on the S<sup>4</sup>C screwdriver D and that the polyaxiality of the screw 11 is blocked.

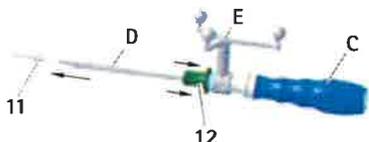


Fig. 7 Picking up the S<sup>4</sup>C screw with the S<sup>4</sup>C screwdriver



**Risk of injury to the patient!**

- Before use, ensure that the selected instrument has been correctly assembled.
  - Ensure that the arrow on the underside of the IGS Tool Star Unit ML is pointing to the tip of the tool.
- Prior to using the instrument with the correctly held screw, perform manual calibration with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
  - Screw in the screw under control with the Brainlab navigation system. When doing so, hold IGS Tool Star Unit ML at the planned indentations with one hand, and turn the S<sup>4</sup>C handle C to screw in the screw 11 with the other hand.

**Smooth-shank screw instruments**



**Risk of injury to the patient!**

- Observe the combination specifications

Instruments for smooth-shank screws are marked with a light-blue ring. They are used to center punch, drill and tap holes for smooth-shank screws Ø 4 mm.



Serious complications for the patient can be caused by incorrect positioning of instruments or implants!

- Carry out operative steps with radiographic visualization.
- When removing the smooth-shank screw awl (FW085R) and during the further operating steps, ensure that the S<sup>4</sup>C navigated smooth-shank screw guide sleeve remains securely fixed in place.
- Ensure that the window on the S<sup>4</sup>C navigated smooth-shank screw guide sleeve is closed during the preparation of the screw hole and while the screw is being inserted, see laser marking on the inner sleeve.
- Take care that no tissue gets caught when opening and closing the window on the S<sup>4</sup>C navigated smooth-shank screw guide sleeve, after the screw has been put in place.

- Mount the Brainlab reflective marker spheres 4 onto the Aesculap star unit G, see Brainlab user manual.
- Retract and hold locking sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2. When doing so, ensure that the recess on the star unit is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

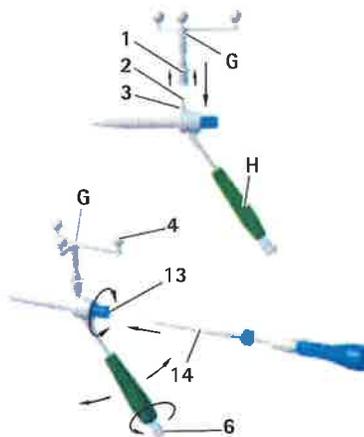


Fig. 8 Mounting the Aesculap star unit on the S<sup>4</sup>C guide sleeve for smooth-shank screws.

## S<sup>4</sup> Cervical – Navigated Instruments



### Risk of injury to the patient!

- **Slide reduction sleeve into the Brainlab Instrument Calibration Matrix Rev. 4, until you hear an audible click.**

- Prior to each use, check the instrument with special reduction sleeve I with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with reduction sleeve I with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that all other instruments (awl, drill, screw tap etc.) are removed for the instrument validation.



Fig. 9 Reduction sleeve for validation/verification with the Brainlab Instrument Calibration Matrix Rev. 4

- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob **6** on the S<sup>4</sup>C handle of the S<sup>4</sup>C guide sleeve H and turn the Aesculap star unit **G** to the desired position, see Fig. 8.
- Once the desired position is reached, tighten knob **6** again.
- Place S<sup>4</sup>C guide sleeve H for smooth-shank screws in the operating field. When doing so, ensure that the window of the guide sleeve is closed during the preparation and insertion of the screw with the guide sleeve, see laser marking on the inner sleeve **13**.
- Center punch the cortical layer of the vertebral body with the smooth-shank screw awl (FW085R), see TAO11984.
- If necessary, insert the awl into the inner sleeve **13** and center punch the bone as far as the stop-position. The stop-position is indicated with a marking on the awl.
- Remove the awl from the operating field.
- Insert the smooth-shank screw drill (FW0865U) **14** with mounted handle (FJ839R) or Intra-handpiece into the inner sleeve **13**.
- Before drilling, the pre-set drill length must be checked with a caliper (e.g. AA845R, Caspar instrument for anterior cervical fusion).
- Under control with the Brainlab navigationssystem, drill a hole in the bone until the adjustable stop-position is reached. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TAO11984).
- Remove the drill from the operating field.
- To prepare the drill holes for the screws, tap the thread with the smooth-shank screw tap (FW087R).

- Insert the smooth-shank screw tap into the inner sleeve and slowly and steadily screw in until the desired depth. When doing so, read the thread depth on the screw tap scale.
- Remove smooth-shank screw tap from the operating field.

### Note

If the S<sup>4</sup>C screw with S<sup>4</sup>C screwdriver FW656R is planned to be inserted under navigation with the guide sleeve H, remove the Aesculap star unit on the S<sup>4</sup>C guide sleeve for smooth-shank screws.



### Risk of injury to the patient!

- **The navigated S<sup>4</sup>C screwdriver FW656R or other screwdrivers are only intended for navigation in the non-navigated S<sup>4</sup>C guide sleeve FW658R.**
- **Navigate the S<sup>4</sup>C screwdriver FW656R, see positioning S<sup>4</sup>C screw under navigation and temporarily fix it in place.**



### Risk of injury to the patient through freely rotating screws!

- **Do not screw in screw so far that the screw head comes into contact with the S<sup>4</sup>C guide sleeve.**

### Note

Use navigated S<sup>4</sup>C screwdriver FW656R only with non-navigated S<sup>4</sup>C guide sleeve FW658R.

- Navigate S<sup>4</sup>C screwdriver, see Positioning S<sup>4</sup>C screw under navigation and temporarily fixing it in place.
- Insert the screw through the S<sup>4</sup>C guide sleeve but do not screw it in completely (smooth shank must remain free). Remove S<sup>4</sup>C screwdriver **D** from the operating field.
- Remove instrument from the screw:
  - Turn the blue inner sleeve **13** and open the window on the S<sup>4</sup>C guide sleeve.
  - Carefully push away S<sup>4</sup>C guide sleeve H laterally from the screw.
  - Remove S<sup>4</sup>C guide sleeve H from the operating field.



### Instruments for Favored Angle screws



- Risk of injury to the patient!**
- Observe the combination specifications

Favored Angle instruments are marked with a gold-colored ring.



- Serious complications for the patient can be caused by incorrect positioning of instruments or implants!**
- Carry out operative steps with radiographic visualization.
  - When removing the obturator (FJ983R) and during the further operating steps, ensure that the S<sup>4</sup>C guide sleeve remains securely fixed in place.

### Drilling holes for Favored Angle screws

- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Mount Aesculap star unit G onto S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm J. When doing so, retract and hold the locking sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C guide sleeve J. When doing so, ensure that the recess is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

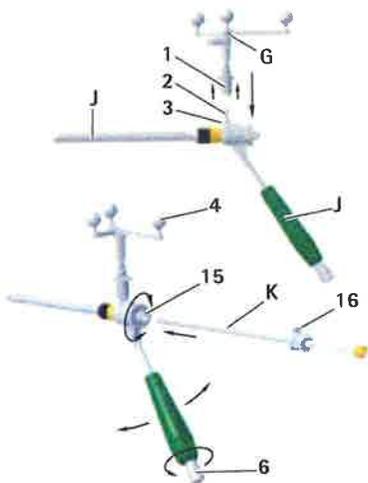


Fig. 10 Mounting the Aesculap star unit onto the S<sup>4</sup>C guide sleeve; inserting the S<sup>4</sup>C drill guide

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide K is mounted prior to this check.
- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide K is mounted prior to this validation.
- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the S<sup>4</sup>C guide sleeve J and turn the Aesculap star unit G to the desired position, see Fig. 10.
- Once the desired position is reached, tighten knob 6 again.
- Then remove inner sleeve guide K again from the S<sup>4</sup>C guide sleeve J.
- Slide obturator (FJ983R) into the inner sleeve 15 of the S<sup>4</sup>C guide sleeve J. The obturator engages in the inner sleeve and can still be rotated.
- Bring S<sup>4</sup>C guide sleeve J with mounted obturator into the operating field through the stab incision and position it in place.
- Press the button 16 on the obturator (FJ983R) and withdraw the obturator from the inner sleeve 15.
- If necessary, slide Apfelbaum trocar (FJ984R) into the inner sleeve 15 and insert into the bone to center punch the screw entry point.
- Remove the trocar from the operating field.
- Push inner sleeve guide K onto the inner sleeve 15. The inner guide sleeve engages on the inner sleeve and can still be rotated, see Fig. 10.
- Insert drill for Favored Angle screws (FW088SU) with mounted handle (FJ839R) or Intra-handpiece into the inner sleeve guide K.
- Drill to the pre-set depth under control with the Brainlab navigation system. The drill depth can be read on the scale on the inner sleeve guide K. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).

#### Note

*So as not to lose the entry opening, keep the drill in the drill hole, press the button 16 on the inner sleeve guide K and push down the guide sleeve until it reaches the stop on the bone surface. Then remove the drill and inner sleeve guide K from the S<sup>4</sup>C guide sleeve J.*

- Press button 16 and remove the inner sleeve guide K from the inner sleeve 15.
- To prepare screw holes, insert the Favored Angle screw tap Ø 4 mm (FW089R) into the inner sleeve 15 and tap. The drill depth can be read on the scale on the screw tap.
- Turn the screw tap counterclockwise until it almost exits the bone.



## S<sup>4</sup> Cervical - Navigated Instruments

**Note**

So as not to lose the entry opening, turn the screw tap counterclockwise until it almost exits the bone. Then turn the inner sleeve 15 counterclockwise and at the same time push down the S<sup>4</sup>C guide sleeve J until it reaches the stop on the bone surface. After that, completely unscrew the Favored Angle tap Ø 4 mm (FW089R) from the bone and together with the inner sleeve 15 remove it from the S<sup>4</sup>C guide sleeve J.

**Inserting the screw**

- Ensure that the inner sleeve 15 has been removed from the S<sup>4</sup>C guide sleeve J by turning it counterclockwise.
- Pick up a suitable Favored Angle screw Ø 4.0 mm with the self-retaining S<sup>4</sup>C screwdriver (FW069R). When doing so, retract and hold the holding sleeve 12 against the spring pressure.

**Note**

The self-retaining function of the instrument prevents the screw from falling off of the S<sup>4</sup>C screwdriver when it is being passed to the operating surgeon

- Press the working end of the S<sup>4</sup>C screwdriver fully into the hexagon of the screw 11.
- Release the holding sleeve 12.
- Screw in the screw under control with the Brainlab navigation system.
- Tighten the screw. When doing so, work through the S<sup>4</sup>C guide sleeve.
- Activate the holding sleeve 12 and release the S<sup>4</sup>C screwdriver from the screw.
- Remove the S<sup>4</sup>C guide sleeve and S<sup>4</sup>C screwdriver from the operating field.

**Standard screw (Ø 3.5 mm) instrumentation with Favored Angle instruments**



**Risk of injury to the patient!**

- Observe the combination specifications

To insert standard screws Ø 3.5 mm with the Favored Angle instruments, instruments L, M and N must also be used. These instruments are marked with a black ring.



Serious complications for the patient can be caused by incorrect positioning of instruments or implants!

- Carry out operative steps with radiographic visualization.
- When removing the obturator (FJ983R) and during the further operating steps, ensure that the guide sleeve remains securely fixed in place.
- Mount the Brainlab reflective marker spheres 4 onto Aesculap star unit G, see Brainlab user manual.
- Mount Aesculap star unit G onto S<sup>4</sup>C navigated guide sleeve Ø 3.5/ 4.0 mm J. When doing so, retract and hold the securing sleeve 1 against the spring pressure in the direction of the arrow.
- Push Aesculap star unit G onto adapter 2 of the S<sup>4</sup>C guide sleeve J. When doing so, ensure that the recess is seated over the pin 3 of the adapter.
- Release locking sleeve 1.

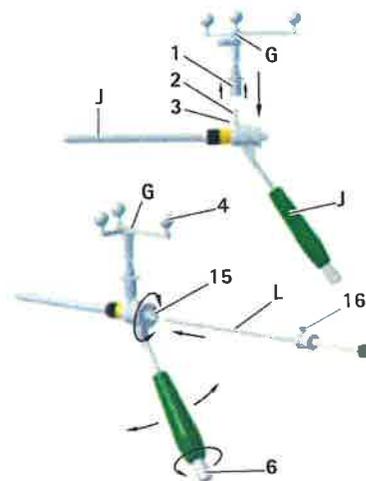


Fig. 11 Mounting the Aesculap star unit onto the S<sup>4</sup>C guide sleeve; inserting the S<sup>4</sup>C drill guide

- Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide L is mounted prior to this check.



- Before using for the first time and before every 10th use, carry out a validation of the instrument with the Brainlab Instrument Calibration Matrix Rev. 4, see Brainlab user manual. Ensure that the inner sleeve guide L is mounted prior to this validation.
- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob 6 on the S<sup>4</sup>C handle of the navigated S<sup>4</sup>C guide sleeve J and turn the Aesculap star unit G to the desired position, see Fig. 11.
- Once the desired position is reached, tighten the knob 6 again.
- Then remove inner sleeve guide L again from the guide sleeve J.
- Slide obturator (FJ983R) into the inner sleeve 15 of the S<sup>4</sup>C guide sleeve J. The obturator engages in the inner sleeve and can still be rotated.
- Bring S<sup>4</sup>C guide sleeve J with mounted obturator into the operating field through the stab incision and position it in place.
- Press the button 16 on the obturator (FJ983R) and withdraw the obturator from the inner sleeve 15.
- If necessary, slide Apfelbaum trocar (FJ984R) into the inner sleeve 15 and insert into the bone to center punch the screw entry point.
- Remove the trocar from the operating field.
- Push inner sleeve guide L onto the inner sleeve 15. The inner sleeve engages on the inner sleeve and can still be rotated, see Fig. 11.
- Insert drill Ø 2.4 mm M with mounted handle (FJ839R) or Intra-hand-piece into the inner sleeve guide L.
- Drill to the pre-set depth under control with the Brainlab navigation system. The drill depth can be read on the scale on the inner sleeve guide L. For further information on drilling, see instructions for use for S<sup>4</sup> Cervical Instruments (TA011984).

**Note**

*So as not to lose the entry opening, keep the drill in the drill hole, press the button 16 on the inner sleeve guide L and push down the guide sleeve until it reaches the stop on the bone surface. Then remove drill and inner sleeve guide L from the S<sup>4</sup>C guide sleeve J.*

- Press button 16 and remove inner sleeve guide L from the inner sleeve 15.
- To prepare screw holes, insert the C1/C2 screw tap Ø 3.5 mm N into the inner sleeve 15 and tap. The drill depth can be read on the scale on the screw tap.

**Note**

*So as not to lose the entry opening, turn the screw tap counterclockwise until it almost exits the bone. Then turn the inner sleeve 15 counterclockwise and at the same time push down the S<sup>4</sup>C guide sleeve J until it reaches the stop on the bone surface. After that, completely unscrew tap N from the bone and together with the inner sleeve 15 remove it from the S<sup>4</sup>C guide sleeve J.*

**Inserting the screw**

- Ensure that the inner sleeve 15 has been removed from the S<sup>4</sup>C guide sleeve J by turning it counterclockwise.
- Pick up a suitable standard screw Ø 3.5 mm with the self-retaining S<sup>4</sup>C screwdriver (FW069R). When doing so, retract and hold the holding sleeve 12 against the spring pressure.

**Note**

*The self-retaining function of the instrument prevents the screw from falling off of the S<sup>4</sup>C screwdriver when it is being passed to the operating surgeon.*

- Press the working end of the S<sup>4</sup>C screwdriver fully into the hexagon of the screw 11.
- Release the holding sleeve 12.
- Screw in the screw under control with the Brainlab navigation system.
- Tighten the screw. When doing so, work through the S<sup>4</sup>C guide sleeve.
- Activate the holding sleeve 12 and release the S<sup>4</sup>C screwdriver from the screw.
- Remove the S<sup>4</sup>C guide sleeve and S<sup>4</sup>C screwdriver from the operating field.



## S<sup>4</sup> Cervical - Navigated Instruments

### Disassembling

#### S<sup>4</sup>C navigated screw tap Ø 3.5 mm, FW655R

- Loosen nut 19 and unscrew from the sleeve 17.
- Remove sleeve 17 together with spring 18 in the direction of the arrow.

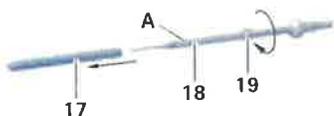


Fig. 12 Disassembling the S<sup>4</sup>C screw tap

#### S<sup>4</sup>C navigated screwdriver, FW656R

- Retract and hold green holding sleeve 22 against the spring pressure.
- Unscrew screw sleeve 20 at the working end of the S<sup>4</sup>C screwdriver and remove it from the shaft.
- Release green holding sleeve 22.
- Push the green holding sleeve 22 with the retaining tongues in the direction of the instrument's working end and remove it from the screwdriver shaft.



Fig. 13 Disassembling the S<sup>4</sup>C screwdriver

#### S<sup>4</sup>C navigated drill guide Ø 3.5 mm, FW654R

- Turn guide sleeve 24 clockwise and remove it. Be aware that it is a left-handed thread.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.

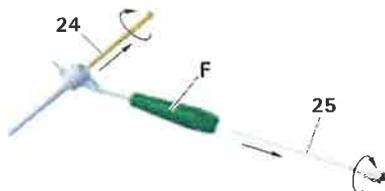


Fig. 14 Disassembling the S<sup>4</sup>C drill guide

#### S<sup>4</sup>C navigated guide sleeve for smooth-shank screws, FW658R

- Turn inner sleeve 26 to the "remove" position and remove it from the outer sleeve in the direction of the arrow.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.

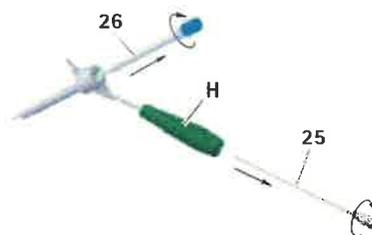


Fig. 15 Disassembling the guide sleeve

#### S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm, FW660R

- Loosen inner sleeve 27 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.
- Loosen knob 25 counterclockwise, unscrew and remove it from the handle by pulling in the direction of the arrow.

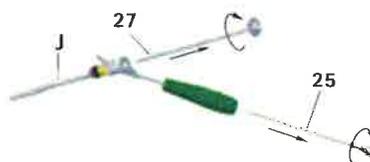


Fig. 16 Disassembling the guide sleeve

### Assembling

#### S<sup>4</sup>C navigated screw tap Ø 3.5, FW655R

- Push guide sleeve 17 together with spring 18 onto the S<sup>4</sup>C navigated screw tap A in the direction of the arrow and turn nut 19 clockwise to tighten it.

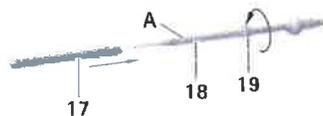


Fig. 17 Assembling the S<sup>4</sup>C navigated screw tap



**S<sup>4</sup>C navigated screwdriver, FW656R**



The S<sup>4</sup>C screwdriver will not function properly if the retaining tongues are bent or kinked!  
 ➤ Do not bend or kink the retaining tongues.

- Push green holding sleeve 22 with retaining tongues 21 onto the screwdriver shaft so that the retaining tongues engage in the grooves 23 of the screwdriver shaft.
- Retract and hold green holding sleeve 22 against the spring pressure.
- Screw screw 20 onto the working end of the S<sup>4</sup>C screwdriver D and tighten it.
- Release green holding sleeve 22.



Fig. 18 Assembling the S<sup>4</sup>C screwdriver

**S<sup>4</sup>C navigated drill guide Ø 3.5 mm, FW654R**

- Screw on guide sleeve 24 counterclockwise. Be aware that it is a left-handed thread. You will hear and feel the guide sleeve clicking into position every half turn.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.

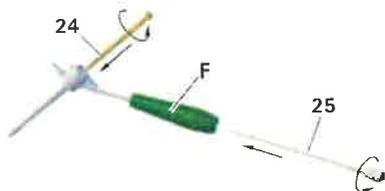


Fig. 19 Assembling the S<sup>4</sup>C drill guide

**S<sup>4</sup>C navigated guide sleeve for smooth-shank screws, FW658R**

- Insert inner sleeve 26 into the outer sleeve in the direction of the arrow in the "remove" position.
- Then turn to "closed" position.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.

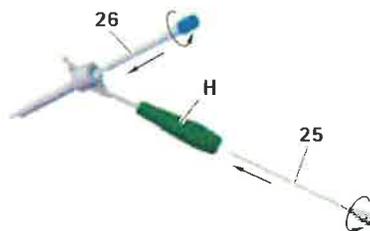


Fig. 20 Assembling the guide sleeve

**S<sup>4</sup>C navigated guide sleeve Ø 3.5/4.0 mm, FW660R**

- Push inner sleeve 27 into the outer sleeve in the direction of the arrow, screw in clockwise and tighten it.
- Push knob 25 into the handle of the instrument, screw in clockwise and tighten it.



Fig. 21 Assembling the guide sleeve

**Validated reprocessing procedure**

*Note*

National laws, national and international standards and directives, and product-specific hygiene regulations for reprocessing must be observed.

*Note*

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

*Note*

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



## S<sup>4</sup> Cervical - Navigated Instruments

### Note

It should be noted that successful reprocessing of this medical device can only be guaranteed following prior validation of the reprocessing method. The operator/sterile processing technician is responsible for this.

### Note

Up-to-date information on reprocessing can be found on the Aesculap Extranet at [www.aesculap-extra.net](http://www.aesculap-extra.net)

### Single-use products



**DANGER**

**Risk of infection of patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!**

➤ **Do not reprocess the product.**

The following products may not be reprocessed.:

- S<sup>4</sup>C C1/C2 drill bit Ø 2.4 mm (FW662SU)
- Standard drill Ø 3.5 mm (FW051SU)
- Favored Angle screw drill (FW088SU)
- Smooth-shank screw drill (FW086SU)

### General information

To prevent increased contamination of loaded instrument trays during use, please ensure that contaminated instruments are collected separately and not returned to the instrument tray.

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion of stainless steel. Therefore the time interval between application and processing should not exceed 6 h; also, neither fixating pre-cleaning 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.

Only process chemicals that have been tested and approved (e.g. VAH/ DGHM 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 regarding temperature, concentration and contact time should 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 process chemicals that cause stress cracks or brittleness in plastics.
  - Clean the product immediately after use.
- Please see [www.a-k-i.org](http://www.a-k-i.org) for more detailed information on hygienically safe reprocessing which is protective of materials and retains their value.
- Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. To prevent foam formation and diminished effectiveness of the process chemicals: Prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water.

### Preparations at the place of use

- Disassemble the product immediately after use, as described in the respective instructions for use.
- Open all valves/faucets.
- Rinse surfaces inaccessible to visual inspection, e.g. in products with hidden gaps or lumens or products with complex geometries, preferably with distilled water, using e.g. a disposable syringe.
- 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.

### Preparation before cleaning

- Disassemble the product prior to cleaning, see Disassembling.

### Cleaning/disinfection



**CAUTION**

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

- Use the cleaning/disinfectant agent according to manufacturer instructions.
- Observe specifications regarding concentration, temperature, and exposure time.
- Do not exceed the maximum allowable cleaning temperature of 55 °C.



- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfection.
  - as an integrated mechanical support measure for mechanical cleaning/disinfection.
  - for additional cleaning of products with residues left after mechanical cleaning/disinfection.

**Note**

For cleaning and disinfecting the IGS Tool Star Unit (pre-calibrated) and the IGS Tool Star Unit ML (calibration with ICM4), see Brainlab user manual.

**FW652R, FW654R, FW658R, FW660R, FW661R and FJ985R**



**Danger to the patient!**  
➤ Only mechanically clean the product.

**Note**

Listed below are the reprocessing procedures approved for the individual system components.

**Manual cleaning with immersion disinfection**

Art. no.	Designation
FW067R	Handle without ratchet <b>C</b>
FW165R	Handle with ratchet <b>C</b>
FW653R	Cortical punch for navigated drill guide FW654R <b>O</b>
FW655R	Navigated screw tap Ø 3.5 mm <b>A</b>
FW656R	Navigated screwdriver for polyaxial screw <b>D</b>
FW657R	Reduction sleeve Ø 13 mm for calibration unit <b>I</b>
FW663R	C1/C2 screw tap Ø 3.5 mm <b>N</b>

**Mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FW653R	Cortical punch for navigated drill guide FW654R <b>O</b>
FW657R	Reduction sleeve Ø 13 mm for calibration unit <b>I</b>
FW663R	C1/C2 screw tap Ø 3.5 mm <b>N</b>

**Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FW652R	Aesculap star unit navigation attachment <b>G</b>
FW654R	Navigated drill guide Ø 3.5 mm, short <b>F</b>
FW655R	Navigated screw tap Ø 3.5 mm <b>A</b>
FW656R	Navigated screwdriver for polyaxial screw <b>D</b>
FW658R	Navigated guide sleeve Ø 4.0 mm for smooth-shank screws <b>H</b>
FW660R	Navigated guide sleeve Ø 3.5/4.0 mm <b>J</b>

**Manual pre-cleaning with ultrasound and brush, and subsequent mechanical alkaline cleaning and thermal disinfection**

Art. no.	Designation
FJ985R	C1/C2 inner sleeve guide Ø 4 mm <b>K</b>
FW661R	C1/C2 inner sleeve guide Ø 3.5 mm <b>L</b>

**Manual cleaning/disinfection**

- Keep working ends open for cleaning.
- When cleaning instruments with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.
- After manual cleaning/disinfection, check visible surfaces visually for residues.
- Repeat the cleaning process if necessary.



Aesculap Spine

S<sup>4</sup> Cervical - Navigated Instruments

## Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Disinfectant Cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Disinfection	RT (cold)	15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
IV	Final rinse	RT (cold)	1	-	FD-W	-
V	Drying	RT	-	-	-	-

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

RT: Room temperature

**Phase I**

- Fully immerse the product in the cleaning/disinfecting solution for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the instrument under running tap water with a suitable cleaning brush where necessary for as long as it takes to remove all discernible residues.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/Ø: 4.5, e.g. TA011944 and brush length: 20/Ø: 2.5, e.g. TE654202 and brush length: 50/Ø: 10, e.g. TA007747) for at least 1 min. or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, joints, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution (at least five times), using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

**Phase II**

- Rinse/flush the instrument 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 instrument in the disinfectant solution.
- Mobilize non-rigid components, such as set screws, joints, etc. during disinfection.
- Rinse lumens at least 5 times at the beginning of the exposure time, using a disposable syringe (20 ml) and an appropriate rinsing adapter. Ensure that all accessible surfaces are moistened.
- Drain any remaining water fully.

**Phase IV**

- Rinse/flush the instrument thoroughly (all accessible surfaces).
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumens at least 5 times, using a disposable syringe (20 ml) and an appropriate rinsing adapter.
- Drain any remaining water fully.

**Phase V**

- Dry the instrument with a lint-free cloth or medical compressed air.



**Mechanical cleaning/disinfecting**

*Note*

*The disinfectant must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark).*

*Note*

*Ensure Ao >3 000 for the process. The disinfectant used for processing must be serviced and checked at regular intervals.*

*Note*

*The disinfectant used for processing must be serviced and checked at regular intervals.*

- Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).
- Connect components with lumens and channels directly to the rinsing port of the injector carriage.
- Place instruments in the tray with their hinges open.

**Mechanical alkaline cleaning and thermal disinfection**

Machine type: Single-chamber cleaning/disinfection device without ultrasound

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	BBRAUN HELIMATIC CLEANER alkaline with tensides, application solution 0.5%
III	Intermediate rinse	>10/50	1	FD-W	-
IV	Thermal disinfection	90/194	5	FD-W	-
V	Drying	-	-	-	According to disinfectant program

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

**Aesculap Spine**

## S<sup>4</sup> Cervical - Navigated Instruments

### Mechanical cleaning/disinfection with manual pre-cleaning

#### Note

The disinfectant must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO 15883).

#### Note

Ensure Ao >3 000 for the process. The disinfectant used for processing must be serviced and checked at regular intervals.

#### Note

The disinfectant used for processing must be serviced and checked at regular intervals.

### Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Disinfectant Cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Rinsing	RT (cold)	1	-	D-W	-

D-W: Drinking water

RT: Room temperature

#### Phase I

- Fully immerse the product in the cleaning/disinfecting solution for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/∅: 4.5, e.g. TA011944 and brush length: 20/∅: 2.5, e.g. TE654202 and brush length: 50/∅: 10, e.g. TA007747) for at least 1 min or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- After cleaning, thoroughly rinse through these components (at least five times) with the cleaning solution, using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

#### Phase II

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



**Manual pre-cleaning with ultrasound and brush**

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Ultrasonic cleaning	RT (cold)	>15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QUAT-free
II	Rinsing	RT (cold)	1	-	D-W	-

D-W: Drinking water  
 RT: Room temperature

**Phase I**

- Mount jaws protection on the product.
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Remove jaws protection.
- Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- For instruments with concealed crevices, lumens or complex geometries, brush non-visible surfaces with a suitable cleaning brush (brush length: 30/∅: 4.5, e.g. TA011944 and brush length: 20/∅: 2.5, e.g. TE654202 and brush length: 50/∅: 3.8, e.g. TA011327) for at least 1 min or as long as it takes to remove all discernible residues.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- After cleaning, use a 20-ml single-use syringe to rinse thoroughly, for at least 5 times, these difficult to access parts of the product.
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

**Phase II**

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



## ***DRAFT SURGICAL TECHNIQUE***

### **Indications for Use**

The S4C Navigation Instruments listed within are intended to assist the surgeon in locating anatomical structures in either open, minimally invasive, or percutaneous procedures. Indication and contraindications are specified in the instruction for use for implants (SOP-AIC-5000169).

The S4C Navigation Instruments are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. These procedures include but are not limited to spinal fusion.

The instruments may only be used with the BrainLab Navigation System. For safe handling prior to the operation, read Spine & Trauma user manual for BrainLab instruments and the corresponding software manual or the BrainLab spine application used.

### **Warnings**

- Always Carry out a function check prior to using the product.
- Handle the instruments with the greatest of care as they are extremely precise and highly sensitive.
- Return dropped or damaged instruments to Aesculap technical service for check of calibration.
- Prior to the operation, plan the configuration of the operating room, the assembly of the instruments and the alignment of the reference star.
- Ensure that the navigation camera has an unrestricted view on the reflective marker spheres of the instruments.
- Use navigated S4C instruments only with Brainlab disposable reflective marker spheres.
- Ensure that the instruments used are not bent or damaged.
- Check the precision of the instruments, particularly that of a fine instrument by holding the instrument tip in the pivot point of the Brainlab Instrument Calibration Matrix.
- Do not reuse sterile and/or single use instruments. Danger to the patient and losdd of instrument functionality are possible due to resterilization!
- Attend appropriate product training before use of the product!

### *Notes:*

*The S<sup>4C</sup> Navigation Surgical Technique Manual should be followed carefully. Important information on the proper usage the instruments are included.*

*Refer to the system's Instructions for Use for additional information on safe handling and preparation, detailed cleaning/disinfection and sterilization information. To obtain a copy of the Instructions for Use, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.*

**Caution: Federal law restricts this device to sale by or on order of a physician.**

## S4 Cervical Navigation Surgical Techniques



### Preparation for Drilling

Center punch the screw holes in the cortical layer for the self tapping S4C screw diameter 3.5 mm , use the S4C navigated drill Guide FW654R together with the S4C cortical punch for Navigated drill guide FW653R

**WARNING: Observe the combination specifications**

**WARNING: Risk of Damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue when inserting the cortical punch without the drill guide FW654R**

Item No.	Description
FW653R	S4C CORT.PUNCH F/NAV.DRILL GUIDE FW654R
FW654R	S4C NAVIGATED DRILL GUIDE D3.5MM SHORT

## S4 Cervical Navigation Surgical Techniques



### Preparation for Drilling

Mount the Brainlab reflective marker spheres on the Aesculap Star Unit. Retract and hold locking sleeve of the Aesculap Star unit against the spring pressure in the direction of the arrow. Push the Aesculap Star unit onto the adapter of the drill guide, ensure the pin of the adapter engages in the recess of the star unit and then release the locking sleeve

Item No.	Description
FW652R	AESCULAP STAR UNIT NAVIGATION ATTACHMENT

## S4 Cervical Navigation Surgical Techniques



### Preparation for Drilling

Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev 4 (see Brainlab users manual). Be sure that the cortical punch is removed.

Make sure that the reflective marker sphere are set to a position that allows an unrestricted view by the camera.

The depth stop position is set by rotating the drill guide inner sleeve

Check the depth by measuring the length of cortical punch exposed past the tip of the drill guide

The punch and guide can then be used to decorticate by pushing the punch forward through the drill guide.

**S4 Cervical Navigation Surgical Techniques**



**Drilling**

The drill is applied through the drill guide and drilled either with use of the manual drill handle FJ839R or with a power drill.

**CAUTION:** The Navigated Drill Guide can only be used for 3.5mm diameter screw placement. For use with Purple 4.0 mm diameter screws us the S4C standard drill guide without the use of navigation.

Item No.	Description
FJ839R	Drill Handle
FW051SU	2.4 mm Drill

**WARNING:**

**Risk of injury from an incorrectly placed hole or a hole that is too deep!**

**Do not sharpen the drill**

**Do not use blunt drills**

**Risk of damage to the spinal cord, nerve roots, adjacent intervertebral space or soft tissue through incorrect drilling!**

**Use only the correct S4C drill guides to drill holes. Insert drill only with the correct drill guide.**

**Before drilling verify the correct pre set depth (e.g. with a caliper)**

**Use the x ray image to select an appropriate drill length prior to the procedure.**

**Align and insert the drill only with the use of radiographic imaging or a navigation system.**

**Select a drill length equivalent to the intended hole depth.**

**Use the lowest drill speed possible**

**Do not bend the drill during the procedure**

## S4 Cervical Navigation Surgical Techniques



**CAUTION:** The S4C Navigated Tap can only be used for 3.5mm diameter screw placement. For use with Purple 4.0 mm diameter screws use the S4C standard Tap without the use of navigation.

### Tapping

S4C screws are self-tapping, however, if the bone quality is found to be hard the surgeon can also pre tap the thread with the S4C navigated screw tap.

#### WARNING:

**Danger:** Prior to use, ensure that the S4C navigated Screw Tap's moveable sleeve retracts correctly

**Be sure that the Instrument is assembled correctly**

**Ensure that the arrow on the underside of the IGS tool Star Unit is pointing to the tip of the tool**

Item No.	Description
FW655R	S4C NAVIGATED SCREW TAP D3.5MM
55830-25A	INSTRUMENT STAR UNIT ML (CALIBR.W/ICM4)
FW165R	S4 RATCHET HANDLE BLUE STR
FW067R	S4C HANDLE W/O RATCHET

Mount the Brainlab reflective marker spheres onto the IGS Tool Star Unit (see Brainlab manual). Push the IGS tool Star Unit onto the shaft of the S4C navigated screw tap. Ensure that the star unit is securely fitted onto the shaft of the S4C screw tap.

*Note: The star unit can be rotated on the shaft of the S4C screw tap.*

Retract and hold the locking sleeve against the spring pressure. Attach S4C handle FW067R or FW165R to S4C navigated screw tap. Release the locking sleeve and then check that the S4C handle is engaged.

## S4 Cervical Navigation Surgical Techniques



### Positioning Screw

To position S4C screws (3.5mm and 4mm diameter) use the S4C navigated screwdriver. Mount the Brainlab reflective marker spheres onto the IGS Tool Star Unit ML (see the Brainlab user manual). Push the IGS Tool Star Unit MI onto the shaft of the S4C Screwdriver. Ensure that the star unit is securely fitted onto the shaft.

*Note: The star unit can be rotated on the shaft of the S4C screwdriver*

Retract and hold locking sleeve against the spring pressure. Mount S4C handle FW067R or FW165R onto S4C screwdriver. Push S4C handle onto the shaft of the S4C Screwdriver. Release locking sleeve and check that the S4C handle is engaged.

### WARNING:

**Use the S4C screwdriver only with IGS Tool Star Unit ML for manual calibration. If you change screws, perform the calibration again!**

## S4 Cervical Navigation Surgical Techniques



### Positioning Screw

*Note: The S4C screwdriver is fitted with a self-retaining function to prevent the S4C screw from falling off.*

Retract and hold the holding sleeve on the S4C Screwdriver. Insert the tip of the S4C screwdriver fully into the hexagon of the screw. Release the holding sleeve. Ensure the screw is securely placed on the S4C screwdriver and that the polyaxiality of the screw is blocked

Prior to using the instrument with the correctly held screw, perform manual calibration with the Brainlab Instrument Calibration Matrix Rev. 4 (see Brainlab manual)

Screw in the screw under guidance of the Brainlab navigation system. When doing so, Hold IGS Tool Star Unit ML at the planned indentions with one hand, and turn the S4C handle to screw in the screw with the other hand.

Item No.	Description
FW656R	S4C NAVIGATED SCREW DRIVER POLYAX.SCREWS
FW165R	S4 RATCHET HANDLE BLUE STR
FW067R	S4C HANDLE W/O RATCHET
55830-25A	INSTRUMENT STAR UNIT ML (CALIBR.W/ICM4)

## S4 Cervical Navigation Surgical Techniques



### Smooth-Shank Screw Placement

Instruments for smooth-shank screws are marked with a light blue ring. They are used to center punch, drill and tap holes for smooth-shank screws.

Mount the Brainlab reflective marker spheres onto the Aesculap Star Unit (see Brainlab user manual). Retract and hold the locking sleeve against the spring pressure in the direction of the arrow. Push Aesculap star unit onto adapter. When doing so, ensure that the recess on the star unit is seated over the pin of the adapter. Then, release the locking sleeve.

### WARNING:

carry out operative steps with radiographic visualization

When removing the smooth-shank awl (FW085R) and during further operating steps, ensure that the S4C navigated smooth-shank screw guide sleeve remains securely fixed in place.

Ensure that the window on the S4C navigated smooth shank screw guide sleeve is closed during the preparation of the screw hole and while the screw is being inserted, see laser marking in the inner sleeve.

Take care that no tissue gets caught when opening or closing the window on the S4C navigated smooth-shank screw guide sleeve after the screw has been put in place.

## S4 Cervical Navigation Surgical Techniques



special reduction sleeve

### Drilling holes for Smooth-Shank Screw Placement

Prior to each use check the instrument with the special reduction sleeve using the Brainlab instrument calibration Matrix Rev 4 (See Brainlab user manual). To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew the knob on the handle of the S4C guide sleeve and turn the Aesculap star unit to the desired position. Then tighten the knob

Place the S4C guide sleeve for smooth-shank screws in the operating field. When doing so, ensure that the window of the guide sleeve is closed during the preparation and insertion of the screw with the guide sleeve. see laser marking on the inner sleeve.

Center Punch the cortical layer of the vertebral body with the smooth-shank screw awl (FW085R)

If necessary, insert the awl into the inner sleeve and center punch the bone as far as the stop position. The stop position is indicated with a marking on the awl.

Remove the awl from the operating field.

Insert the smooth-shank drill FW086SU with mounted handle or power.

Before drilling the pre-set drill depth must be checked with a caliper

Under the guidance of the Brainlab navigation system, drill a hole in the bone until the adjustable stop position is reached

remove the drill from the operating field

## S4 Cervical Navigation Surgical Techniques



### Tapping holes for Smooth-Shank Screw Placement

To prepare to place screws into the drilled holes, tap the threads with smooth shank tap FW087R

Insert the smooth-shank screw tap into the inner sleeve and slowly and steadily screw in to the desired depth. A depth scale is located on the tap.

Remove the tap from the operating field.

### **WARNING:**

**Do not screw the screw is so far that the screw comes in contact with the S4C guide sleeve.**

## S4 Cervical Navigation Surgical Techniques



**WARNING:**

Navigate the Screwdriver FW656R in combination with S4C Guide sleeve FW658R which will not be navigated

**Smooth-Shank Screw Placement**

Navigate S4C Screwdriver. Insert the Screw through the S4C Guide sleeve but do not screw it in completely (Smooth Shank portion not into the bone).

Remove the screwdriver

Turn the blue inner sleeve of the S4C guide sleeve so that the window "opens"

Carefully push away the S4C guide sleeve laterally from the screw.

Remove the S4C guide sleeve from the operating field.

Item No.	Description
FW658R	S4C NAVIG.GUIDE SLEEVE D4.0/SMOOTH SHANK
FW657R	REDUCING SLEEVE D13MM F/CALIBRATION TOOL
FW656R	S4C NAVIGATED SCREW DRIVER POLYAX.SCREWS
FW165R	S4 RATCHET HANDLE BLUE STR
FW067R	S4C HANDLE W/O RATCHET
55830-25A	INSTRUMENT STAR UNIT ML (CALIBR.W/ICM4)

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## S4 Cervical Navigation Surgical Techniques

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### **Favoured Angle Screw Placement- Preparing for Drilling**

Mount the Brainlab reflective marker spheres on the Aesculap Star Unit. Retract and hold locking sleeve of the Aesculap Star unit against the spring pressure in the direction of the arrow. Push the Aesculap Star unit onto the adapter of the drill guide, ensure the pin of the adapter engages in the recess of the star unit and then release the locking sleeve.

Prior to each use, check the instrument with the Brainlab Instrument Calibration Matrix Rev 4 (see Brainlab users manual). Be sure that the cortical punch is removed.

Make sure that the reflective marker sphere are set to a position that allows an unrestricted view by the camera.

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## S4 Cervical Navigation Surgical Techniques

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### Favoured Angle Screw Placement- Tapping

Insert the Favoured Angle screw tap for 4mm dia screws FW089R and tap. The depth is etched onto the shaft of tap for visual indication.

Turn the screw tap counterclockwise until it almost exits the bone. Turn the inner sleeve counterclockwise while pushing down until it stops on the bone surface. Then completely unscrew the tap from the bone and remove it and the inner sleeve guide at the same time. This will keep the instrument on the entry site for screw insertion.



## S4 Cervical Navigation Surgical Techniques



### Favoured Angle Screw Placement

Pick up the suitable Favoured Angle screw with the self-retaining S4C screwdriver FW069R by retracting and holding the holding sleeve against the spring pressure. Then press the working end of the screwdriver into the hexagon of the screw. When fully inserted, release the holding sleeve.

Screw in the screw under the guidance of the Brainlab navigation system.

To release the screwdriver from the screw retract the holding sleeve and remove the screwdriver from the screw.

Remove the S4C guide sleeve and the S4C screwdriver from the operating field

#### WARNING:

Observe the combination specifications

Carry out operative steps with radiographic visualization

Ensure the guide sleeve remains securely fixed in place.

#### Note:

The Favoured angle procedure can also be utilized to place 3.5 polyaxial screws if there is a preference for this instrument. If so, Make sure to use instruments ( FW661R Inner drill guide for 3.5 mm screws), FW663R (Tap for 3.5 mm screws), FW662SU (drill for 3.5mm Screws)

Item No.	Description
FW660R	S4C NAVIGATED GUIDE SLEEVE D3.5/4.0MM
FJ985R	APFELBAUM INNER SLEEVE GUIDE D 4.0MM
FW661R	S4C INNER SLEEVE GUIDE D3.5MM
FW662SU	S4C DRILL BIT D2.4MM
FW663R	S4C SCREW TAP 3.5MM

## **S4 Cervical Navigation Surgical Techniques**

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DRAFT

6/8/2013

Aesculap Implant Systems

# **ATTACHMENT E**

























