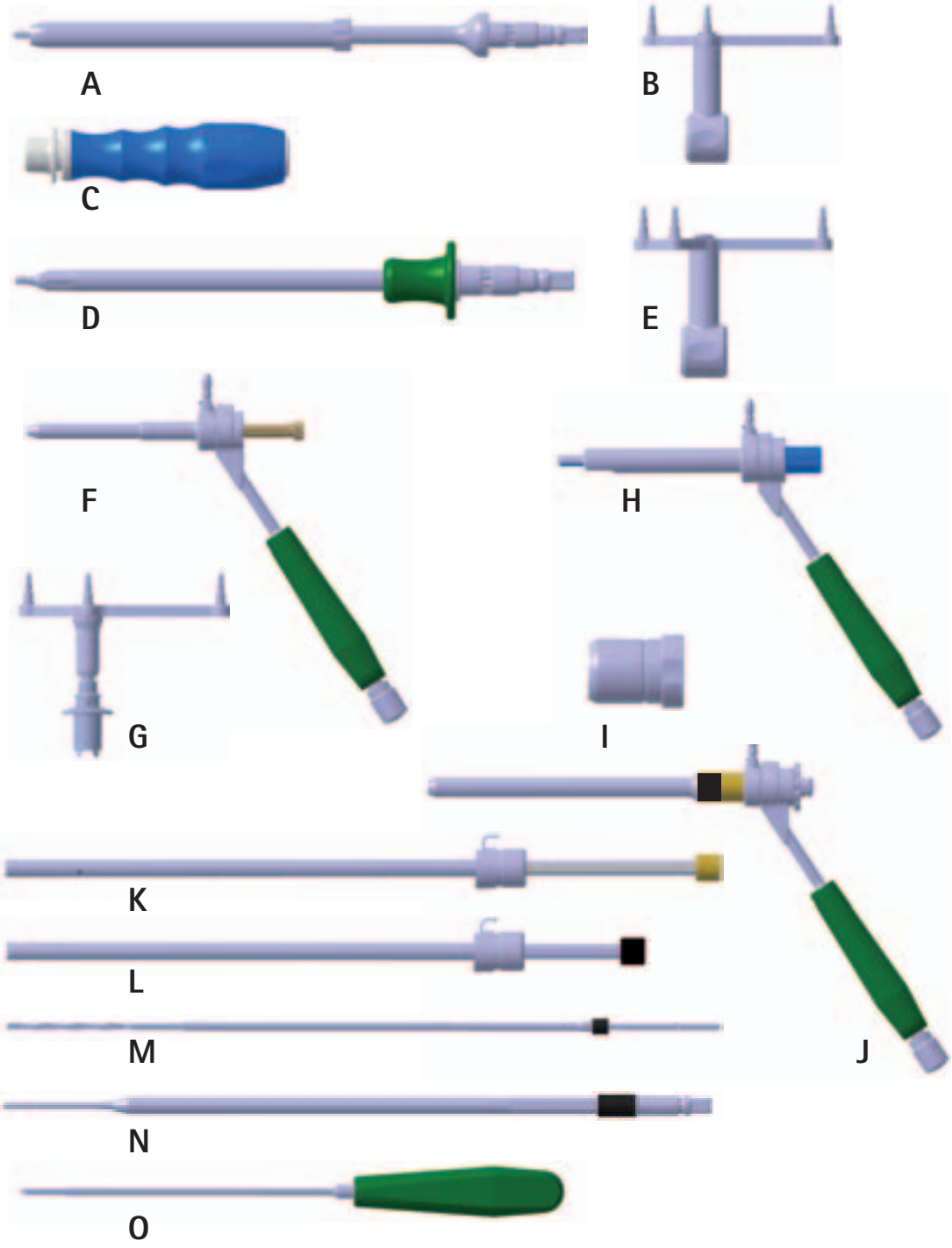
Aesculap Spine

GB **Instructions for use/Technical description**
USA S^4 Cervical - Navigated Instruments

B BRAUN
SHARING EXPERTISE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S^4 Cervical - Navigated Instruments

Legend

A Navigated screw tap ∅ 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 ∅ 3.5 mm, short (FW654R)

G Aesculap star unit Navigation attachment (FW652R)

H Navigated guide sleeve ∅ 4.0 mm for smooth-shank screws (FW658R)

I Reduction sleeve ∅ 13 mm for Brainlab Instrument Calibration Matrix Rev. 4 (FW657R)

J Navigated guide sleeve ∅ 3.5/4.0 mm (FW660R)

K C1/C2 inner sleeve guide ∅ 4 mm (FJ985R)

L C1/C2 inner sleeve guide ∅ 3.5 mm (FW661R)

M C1/C2 drill bit ∅ 2.4 mm (FW662SU)

N C1/C2 screw tap ∅ 3.5 mm (FW663R)

O Cortical punch for navigated drill guide FW654R (FW653R)

Symbols on product and packages

Symbol	Explanation
STERILE R	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 during the navigation of pedicle screws (T1-T3).

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^4C navigated drill guide **F** with:
  - S^4C-cortical punch for S^4C-drill guide **O**
  - Standard drill bit, ∅ 2.4 mm for ∅ 3.5 mm screws (FW051SU)
- Only combine S^4C navigated guide sleeve ∅ 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^4C navigated guide sleeve ∅ 3.5/4.0 mm **J** with:
  - approved Apfelbaum C1/C2 obturator (FJ983R)
  - Apfelbaum trocar (FJ984R)
  - Favored Angle screw drill ∅ 2.9 mm for ∅ 4 mm screws (FW088SU)
  - Favored Angle screw tap ∅ 4 mm (FW089R)
  - C1/C2 inner sleeve guide ∅ 4 mm **K** (FJ985R)
  - S^4C Favored Angle screwdriver (FW069R)
  - C1/C2 drill bit ∅ 2.4 mm for ∅ 3.5 mm screws (FW662SU) **M**
  - C1/C2 screw tap ∅ 3.5 mm (FW663R) **N**
  - C1/C2 inner sleeve guide ∅ 3.5 mm (FW661R) **L**
  - Apfelbaum ball end screwdriver (FJ988R)

Note

K-wires generally may not be used with the S^4C 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).

∅ S^{4}C1/C2 drill bit 2.4 mm (FW662SU), standard drill ∅ 2.4 mm (FW051SU), Favored Angle screw drill ∅ 2.9 mm (FW088SU) and drill ∅ 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^{4}C instruments with the greatest of care as they are extremely precise and highly sensitive.**
- **Check accurate calibration of dropped or damaged S^{4}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^{4}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^4 Cervical - Navigated Instruments

Preparing holes for S^{4}C screws with navigation

WARNING

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^{4}C screws ∅ 3.5 mm with navigation, use the S^{4}C navigated drillguide ∅ 3.5 mm **F** only together with S^{4}C cortical punch for S^{4}C navigated drill guide **O**.

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

WARNING

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^{4}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**.

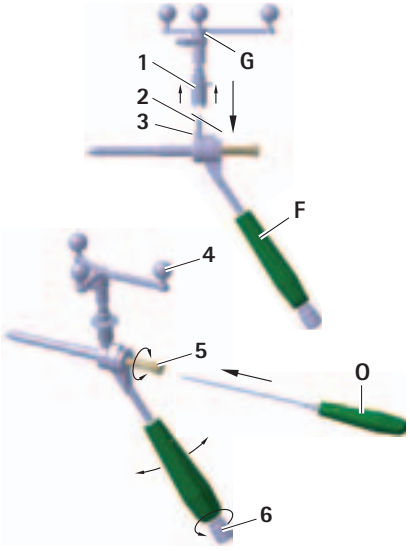

Fig. 1 Mounting the Aesculap star unit on S^{4}C drill guide FW654R

- 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^{4}C handle of the S^{4}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^{4}C drill guide **F**. The maximum depth is 6 mm.
- Insert S^{4}C cortical punch **O** into S^{4}C drill guide **F**.
- Check the pre-set center punch depth with a caliper (e.g. AA845R).
- To open the cortical bone, press S^{4}C cortical punch to the preset depth under control with the Brainlab navigation system.

Drilling holes for the S^{4}C screws

DANGER

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^{4}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)

DANGER

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

- **Use only the correct S^{4}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.

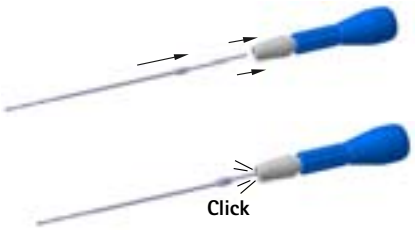

Fig. 2 Assembling the drill

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^{4}C screws ∅ 3.5 mm

WARNING

Risk of injury to the patient!

- **Observe the combination specifications**

For controlled drilling of the holes for S^{4}C-screws ∅ 3.5 mm with standard drill ∅ 2.4 mm (FW051SU), the S^{4}C navigated drill guide ∅ 3.5 mm **F** (FW654R) must always be used.

Note

*The drill ∅ 2.9 mm (FW052SU) may not be used with S^{4}C navigated drill guide **F**.*

To drill the holes for the screws with ∅ 4 mm, use standard drill guide FW053R without navigation, see instructions for use for S^4 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^{4}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**.

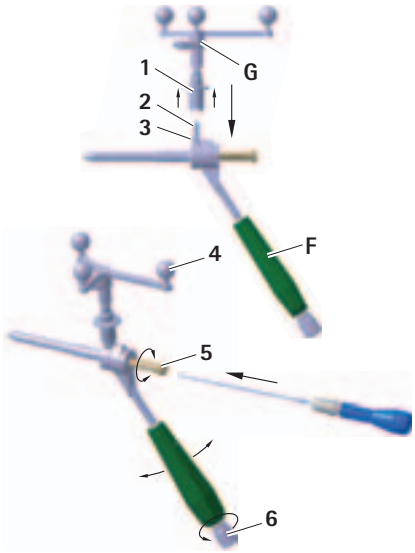

Fig. 3 Mounting the Aesculap star unit on S^{4}C drill guide FW654R

- 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^{4}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^{4}C drill guide **F**.
- Insert the drill with mounted handle or Intra-handpiece into S^{4}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^4 Cervical - Navigated Instruments

Tapping (optional)

S^4C 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^4C screw tap.

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

DANGER

Risk of tissue injury when using the S^4C screw tap (A) and damage to bone thread!

- **Prior to using the S^4C 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^4C navigated screw tap **A**. Ensure that the star unit is securely fitted onto the shaft of the S^4C screw tap.

Note

The star unit can be rotated on the shaft of the S^4C screw tap.

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

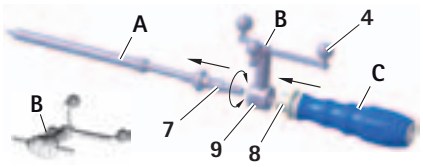

Fig. 4 Mounting the IGS Tool Star Unit and S^4C handle onto the S^4C screw tap

WARNING

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^4C 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^4C screw tap to read the depth during the tapping process, see Fig. 5.

Fig. 5 Screw tap with readable thread depth

Positioning S^4C screw under navigation and temporarily fixing it in place

DANGER

Risk of injury to the patient!

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

- To position S^4C screws ∅ 3.5 mm and ∅ 4 mm under navigation, use S^4C 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^4C screwdriver **D**. Ensure that the star unit is securely fitted onto the shaft of the S^4C screwdriver.

Note

The star unit can be rotated on the shaft of the S^4C screwdriver.

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

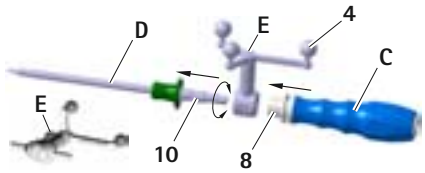

Fig. 6 Mounting the IGS Tool Star Unit and S^4C handle (FW067R or FW165R) onto the S^4C screwdriver

Note

The S^{4}C screwdriver is fitted with a self-retaining function to prevent the S^{4}C screw from falling off when it is passed to the surgeon.

- Retract and hold holding sleeve **12** on the S^{4}C screwdriver **D**.
- Insert the tip of the S^{4}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^{4}C screwdriver **D** and that the polyaxiality of the screw **11** is blocked.

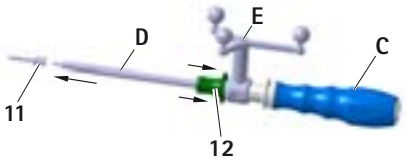

Fig. 7 Picking up the S^{4}C screw with the S^{4}C screwdriver

DANGER

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^{4}C handle **C** to screw in the screw **11** with the other hand.

Smooth-shank screw instruments

WARNING

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 ∅ 4 mm.

DANGER

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^{4}C navigated smooth-shank screw guide sleeve remains securely fixed in place.**
- **Ensure that the window on the S^{4}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^{4}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**.

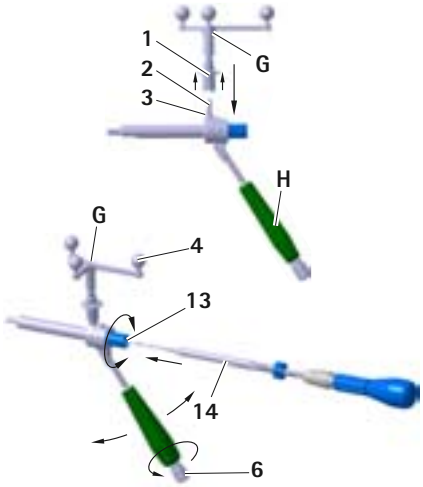

Fig. 8 Mounting the Aesculap star unit on the S^{4}C guide sleeve for smooth-shank screws.

S^4 Cervical - Navigated Instruments

DANGER

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.

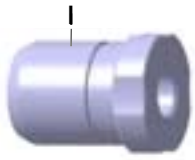

Fig. 9 Reduction sleeve for validation/verification with the Brainlab Instrument Calibration Matrix Rev. 4

- To ensure the camera has an unrestricted view of the reflective marker spheres, unscrew knob **6** on the S^4C handle of the S^4C 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^4C 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. 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^4 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^4C screw with S^4C screwdriver FW656R is planned to be inserted under navigation with the guide sleeve **H**, remove the Aesculap star unit on the S^4C guide sleeve for smooth-shank screws.*

DANGER

Risk of injury to the patient!

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

DANGER

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^4C guide sleeve.**

Note

Use navigated S^4C screwdriver FW656R only with non-navigated S^4C guide sleeve FW658R.

- Navigate S^4C screwdriver, see Positioning S4C screw under navigation and temporarily fixing it in place.
- Insert the screw through the S^4C guide sleeve but do not screw it in completely (smooth shank must remain free). Remove S^4C screwdriver **D** from the operating field.
- Remove instrument from the screw:
  - Turn the blue inner sleeve **13** and open the window on the S^4C guide sleeve.
  - Carefully push away S^4C guide sleeve **H** laterally from the screw.
  - Remove S^4C guide sleeve **H** from the operating field.

Instruments for Favored Angle screws

WARNING

Risk of injury to the patient!

- **Observe the combination specifications**

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

DANGER

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^{4}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^{4}C navigated guide sleeve ∅ 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^{4}C guide sleeve **J**. When doing so, ensure that the recess is seated over the pin **3** of the adapter.
- Release locking sleeve **1**.

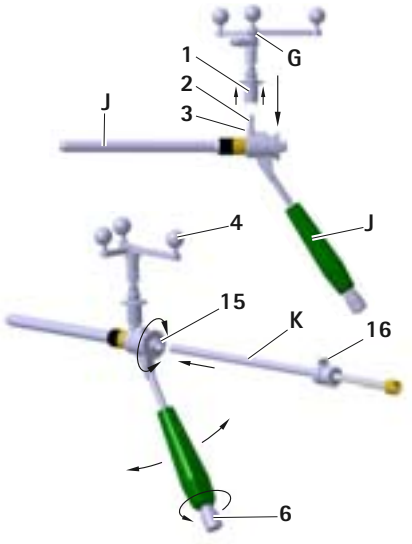

Fig. 10 Mounting the Aesculap star unit onto the S^{4}C guide sleeve; inserting the S^{4}C drill guide

- 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^{4}C handle of the S^{4}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^{4}C guide sleeve **J**.
- Slide obturator (FJ983R) into the inner sleeve **15** of the S^{4}C guide sleeve **J**.

  The obturator engages in the inner sleeve and can still be rotated.
- Bring S^{4}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^4 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^{4}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 ∅ 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.

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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 S4C guide sleeve **J** until it reaches the stop on the bone surface. After that, completely unscrew the Favored Angle tap ∅ 4 mm (FW089R) from the bone and together with the inner sleeve **15** remove it from the S4C guide sleeve **J**.*

Inserting the screw

- Ensure that the inner sleeve **15** has been removed from the S4C guide sleeve **J** by turning it counterclockwise.
- Pick up a suitable Favored Angle screw ∅ 4.0 mm with the self-retaining S4C 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 S4C screwdriver when it is being passed to the operating surgeon

- Press the working end of the S4C 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 S4C guide sleeve.
- Activate the holding sleeve **12** and release the S4C screwdriver from the screw.
- Remove the S4C guide sleeve and S4C screwdriver from the operating field.

Standard screw (∅ 3.5 mm) instrumentation with Favored Angle instruments

WARNING

Risk of injury to the patient!

- **Observe the combination specifications**

To insert standard screws ∅ 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.

DANGER

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 S4C navigated guide sleeve ∅ 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 S4C guide sleeve **J**. When doing so, ensure that the recess is seated over the pin **3** of the adapter.
- Release locking sleeve **1**.

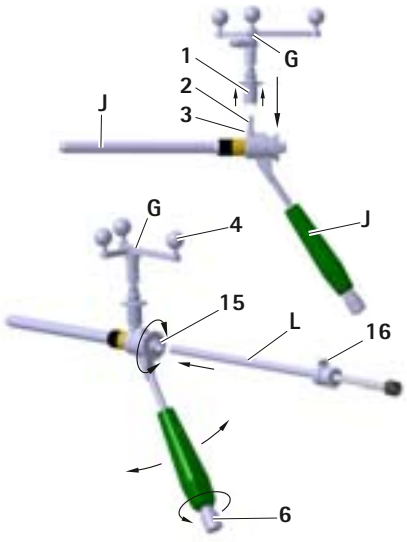

Fig. 11 Mounting the Aesculap star unit onto the S4C guide sleeve; inserting the S4C drill guide

- 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^{4}C handle of the navigated S^{4}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^{4}C guide sleeve **J**. The obturator engages in the inner sleeve and can still be rotated.
- Bring S^{4}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 ∅ 2.4 mm **M** with mounted handle (FJ839R) or Intra-handpiece 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^4 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^{4}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 ∅ 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^{4}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^{4}C guide sleeve **J**.*

Inserting the screw

- Ensure that the inner sleeve **15** has been removed from the S^{4}C guide sleeve **J** by turning it counterclockwise.
- Pick up a suitable standard screw ∅ 3.5 mm with the self-retaining S^{4}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^{4}C screwdriver when it is being passed to the operating surgeon.

- Press the working end of the S^{4}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^{4}C guide sleeve.
- Activate the holding sleeve **12** and release the S^{4}C screwdriver from the screw.
- Remove the S^{4}C guide sleeve and S^{4}C screwdriver from the operating field.

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Disassembling

S4C navigated screw tap ∅ 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.

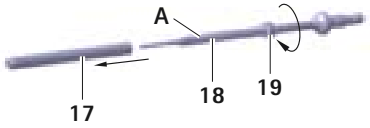

Fig. 12 Disassembling the S4C screw tap

S4C navigated screwdriver, FW656R

- Retract and hold green holding sleeve **22** against the spring pressure.
- Unscrew screw sleeve **20** at the working end of the S4C 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.

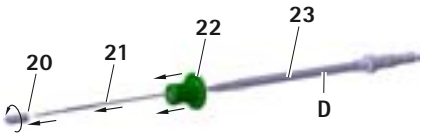

Fig. 13 Disassembling the S4C screwdriver

S4C navigated drill guide ∅ 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.

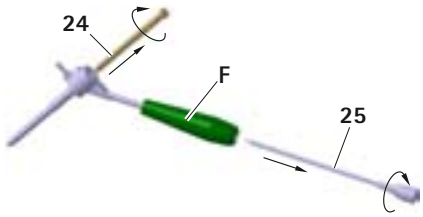

Fig. 14 Disassembling the S4C drill guide

S4C 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.

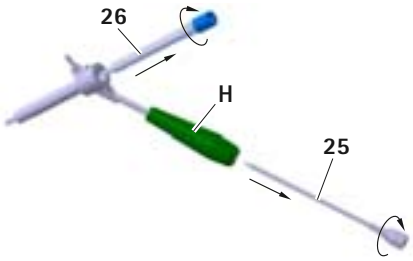

Fig. 15 Disassembling the guide sleeve

S4C navigated guide sleeve ∅ 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.

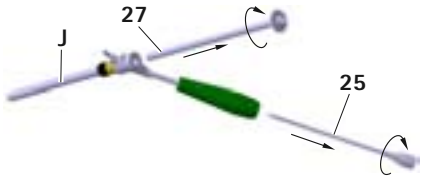

Fig. 16 Disassembling the guide sleeve

Assembling

S4C navigated screw tap ∅ 3.5, FW655R

- Push guide sleeve **17** together with spring **18** onto the S4C navigated screw tap **A** in the direction of the arrow and turn nut **19** clockwise to tighten it.

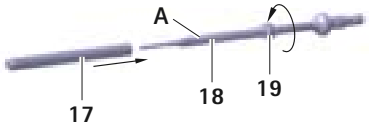

Fig. 17 Assembling the S4C navigated screw tap

S^{4}C navigated screwdriver, FW656R

CAUTION

The S^{4}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^{4}C screwdriver **D** and tighten it.
- Release green holding sleeve **22**.

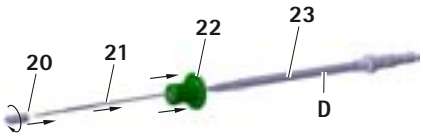

Fig. 18 Assembling the S^{4}C screwdriver

S^{4}C navigated drill guide ∅ 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.

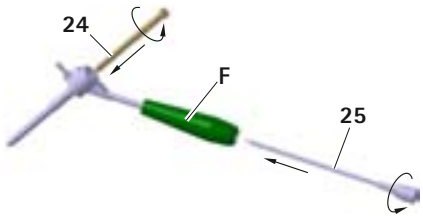

Fig. 19 Assembling the S^{4}C drill guide

S^{4}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.

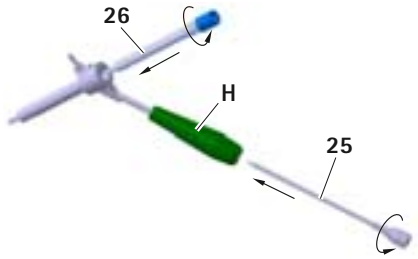

Fig. 20 Assembling the guide sleeve

S^{4}C navigated guide sleeve ∅ 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.

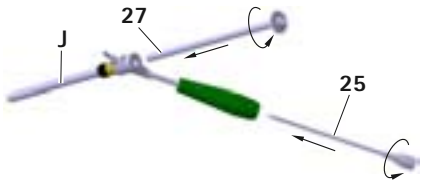

Fig. 21 Assembling the guide sleeve

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.

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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

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.:

- S4C C1/C2 drill bit ∅ 2.4 mm (FW662SU)
- Standard drill ∅ 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 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

WARNING

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 **C**
FW165R	Handle with ratchet **C**
FW653R	Cortical punch for navigated drill guide FW654R **O**
FW655R	Navigated screw tap ∅ 3.5 mm **A**
FW656R	Navigated screwdriver for polyaxial screw **D**
FW657R	Reduction sleeve ∅ 13 mm for calibration unit **I**
FW663R	C1/C2 screw tap ∅ 3.5 mm **N**

Mechanical alkaline cleaning and thermal disinfection

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

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

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

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

Art. no.	Designation
FJ985R	C1/C2 inner sleeve guide ∅ 4 mm **K**
FW661R	C1/C2 inner sleeve guide ∅ 3.5 mm **L**

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.

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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/∅: 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 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 disinfector 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 disinfector used for processing must be serviced and checked at regular intervals.

Note

The disinfector 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 alcaline 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)

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Mechanical cleaning/disinfection with manual pre-cleaning

Note

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

Note

The disinfector 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 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 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.

S4 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 alcaline 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

CAUTION

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^{-6}, Aesculap recommends the following parameters:

Aesculap Orga Tray/sterile container (perforated bottom) Minimum cycle parameters*			
Sterilization method	**Temp.**	**Time**	**Minimum drying time**
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

WARNING

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
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Center Valley, PA 18034
USA