❶ Select **TOOL CALIBRATION** from the **INTERFACE SOFTWARE**.
❷ Select the **HEADSET** to be used for calibration.

Note: The **HEADSET** is listed by its serial number or its pairing name. See *Headset Pairing* on page 5-3 for more information.

❸ Select a surgical instrument to be calibrated. For instruments in a swivel Universal Tool Adaptor, lock the swivel before continuing.

Note: None of the names is specific, except for the Screwdriver. If the generic name is not appropriate, choose **Other**.

❹ Take one of the prepared surgical instruments and touch the tip of the tool to the calibration point on the patient marker.
❺ Press the **Start** button (located on the bottom left of the screen) and swivel the tool, keeping the tip on the point.
❻ Make sure that the tool marker and patient marker are both within the field of view of the Headset and displayed on the **INTERFACE SOFTWARE**.
❼ When both markers have been located tap **Capture**.

After the message **Calibration Succeed** continue with as many tools as required for the surgical procedure.

6.4. Patient Preparation

Once the patient is positioned on the OR table and anesthetized, the surgeon performs the following:

1. Selects one of two clamp types to attach to the spinous processes to serve as the anchoring point
2. Registers the patient using one of two registration marker methods
3. Performs an intraoperative 3D scan

Note: It is recommend to make a preview 2D scan to ensure that the registration marker and patient are in the field of view.

6.4.1. Patient Clamp

The surgeon selects one of two types of patient clamps to be connected to the spinous process of the patient during the procedure according to the requirements of the procedure.

- The Patient Clamp—Straight is recommended for open back surgery, levels with small vertebrae, or when performing sacral-L5
- The Patient Clamp—Arc is recommended for minimally invasive surgery

Once connected to the spinous process, a patient marker is secured to the top of the clamp to provide a rigid reference point of the patient's spine, enabling system registration and tracking of the position of the surgical tools, relative to the patient's vertebra, throughout the procedure.

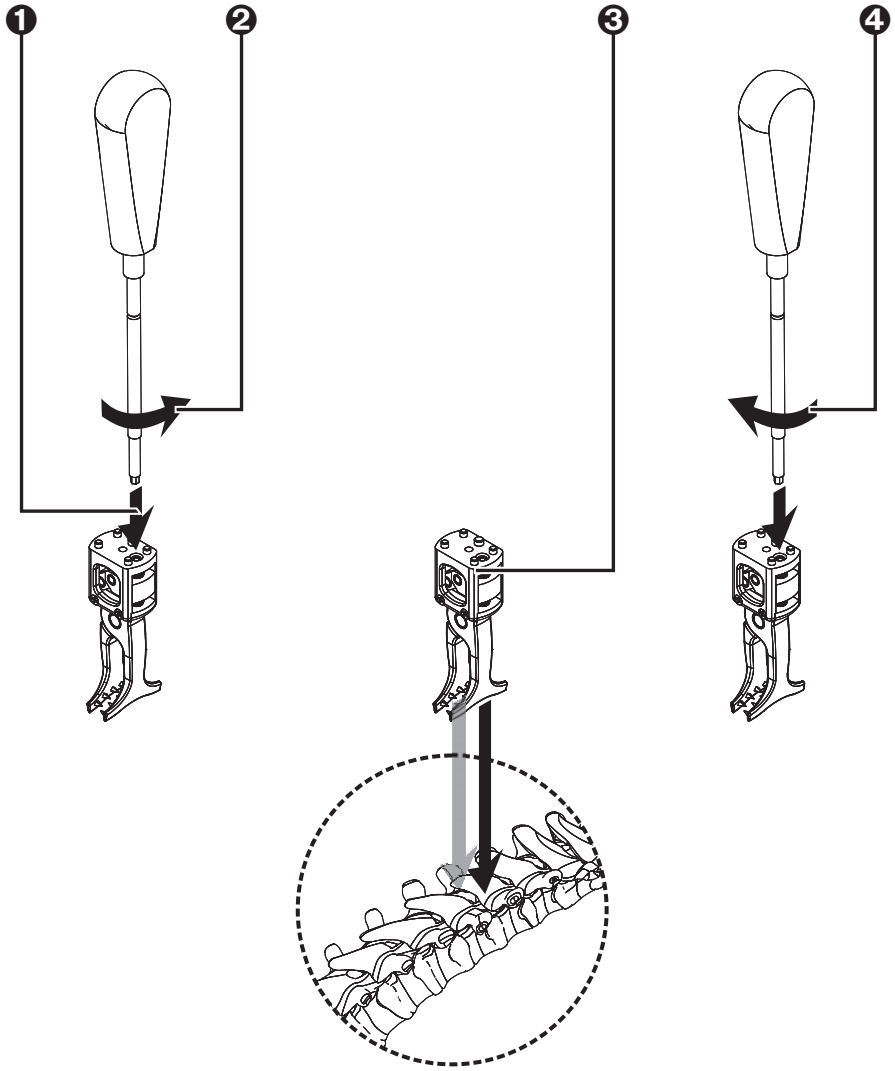
Patient clamps are reusable components of the **XVS** system. Once disconnected from the spinous process at the end of the procedure they must be cleaned and autoclaved prior to the next procedure. See *Cleaning Reusable Components* on page 8-1 for more information.

Warning: Discard clamps that become scratched, or when the anodized surface is compromised.

Patient Clamp—Straight

The Patient Clamp—Straight is generally used for open back surgery. In this procedure a midline incision is made by the surgeon on the patient's back at the operated spine area.

Figure 11: Patient Clamp—Straight Attachment



❶ Insert the allen screwdriver into the adjustment screw of the Patient Clamp—Straight.
❷ Turn the allen screwdriver in a counter-clockwise direction to open the clamp jaws.
❸ Attach the clamp to the spinous processes in the operated area.
❹ Use the allen screwdriver close the Patient Clamp—Straight tightly on the spinous processes.

Warning: Do not over-tighten the clamp, as this may damage the spinous processes.

Warning: The available working area is two vertebrae above and three below the base of the clamp.

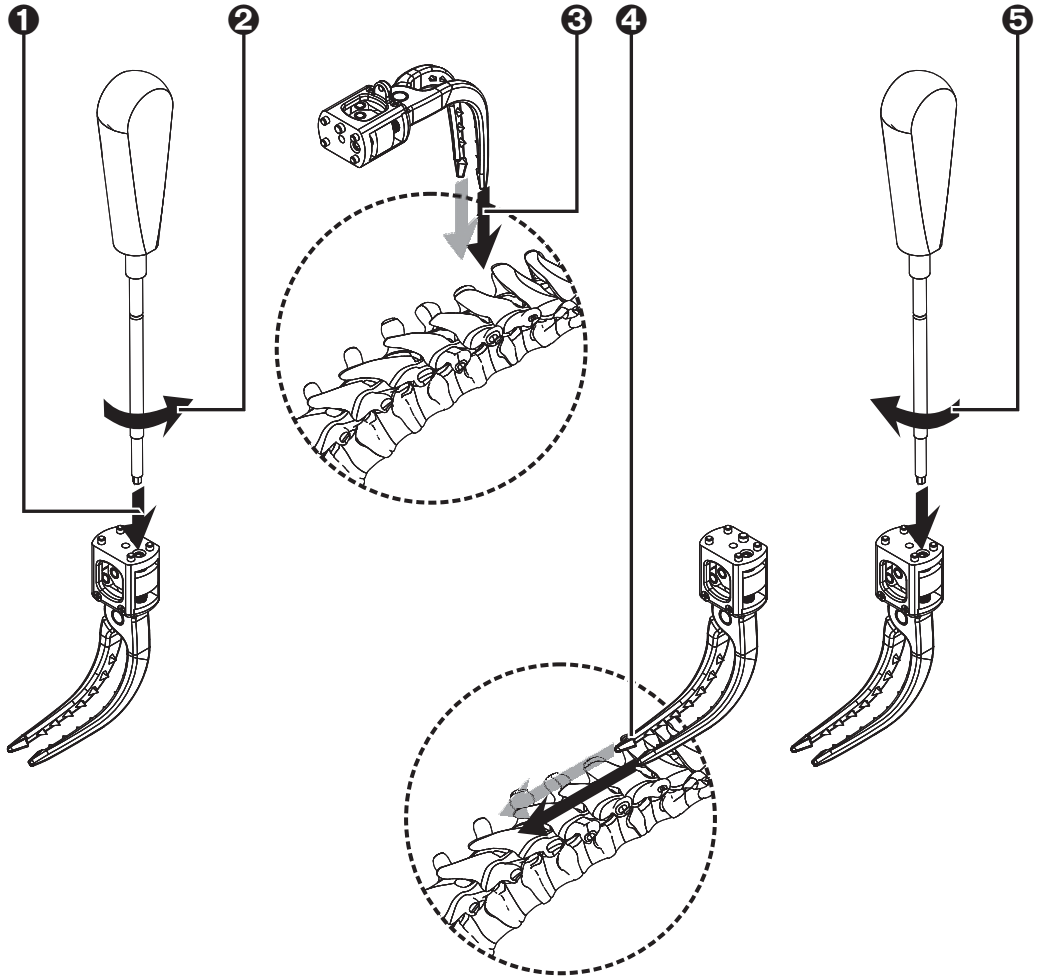
Warning: Verify that the clamp is closed tightly enough on the spinous processes so that it does not move during the surgical procedure.

Patient Clamp—Arc

The Patient Clamp—Arc is generally used for minimally invasive surgery using a small incision in the patient's back.

The recommended direction is to place the clamp in the cranial to caudal direction with the pointed end pointing caudally.

Figure 12: Patient Clamp—Arc Attachment



❶ Insert the allen screwdriver into the adjustment screw of the Patient Clamp—Arc.
❷ Turn the allen screwdriver in a counter-clockwise direction to open the clamp jaws.
❸ Slide the tweezers of the clamp through the incision with the teeth facing caudal direction.
❹ Rotate the clamp and attach it to the spinous processes in the operated area.
❺ Use the allen screwdriver to close the Patient Clamp—Arc tightly on the spinous processes.

Warning: Do not over-tighten the clamp, as this may damage the spinous processes.

Warning: The available working area is two vertebrae above and three below the base of the clamp.

Warning: Verify that the clamp is closed tightly enough on the spinous processes so that it does not move during the surgical procedure.

6.4.2. Patient Registration

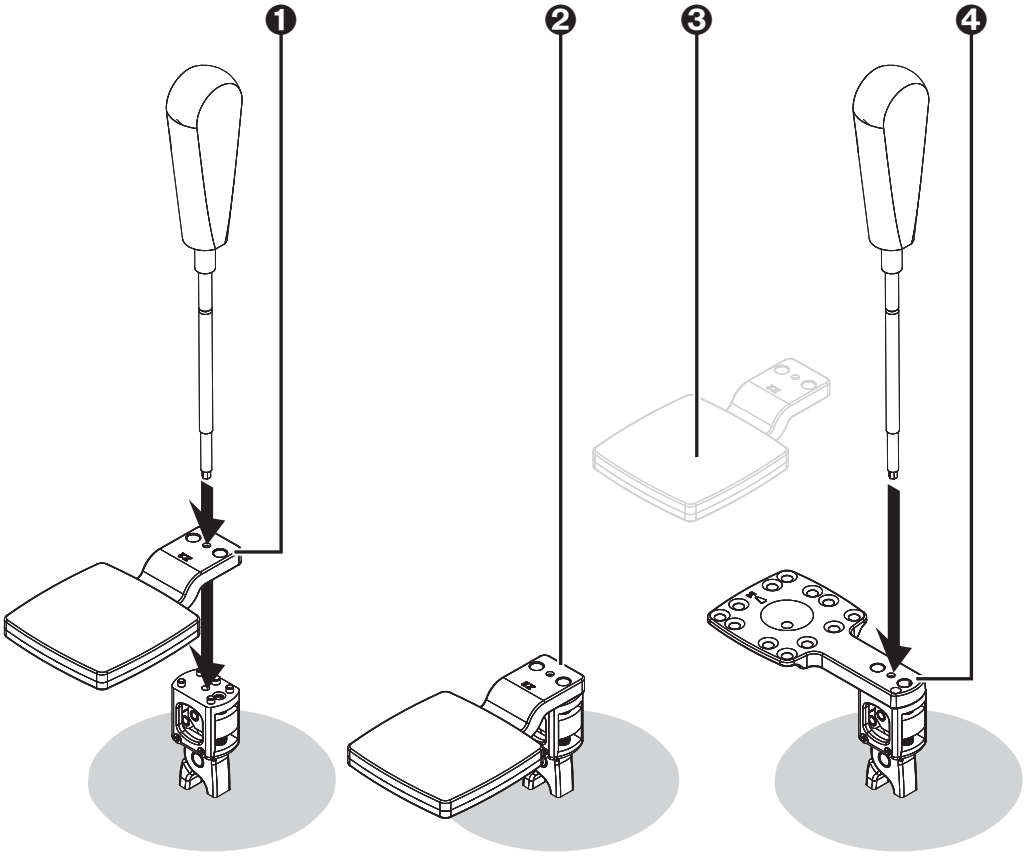
Patient registration is the process whereby the **XVISION-SPINE** system orients the transformation between the patient scan and the patient marker. There are two options for patient registration, based on type of 3D intraoperative scanner and patient anatomy.

Z-Marker Registration

Patient registration using Z-Markers is the simplest and quickest registration method, and is the recommended procedure.

However, it may not be suitable, either because of the patient's anatomy or because the intraoperative 3D scan cannot include both the Z-Marker and the area of the spine intended for the procedure because of its limited field of view. In that case proceed with *X-Marker Registration* (page 6-11).

Figure 13: Z-Marker Registration



❶ Attach the Z-Marker to the patient clamp with the allen screwdriver. Choose either the Z-Marker-10 or Z-Marker-40 so it will be as close as possible to the surface of the patient's body.
❷ Initiate an intraoperative 3D scan of the area, verifying that the Zlink patient marker is included in the scan.
❸ Remove the Z-Marker and set it aside for cleaning and sterilization. See *Cleaning Reusable Components* on page 8-1 for more information.
❹ Attach the patient marker to the patient clamp with the allen screwdriver.

Continue with *New Study* (page 7-1).

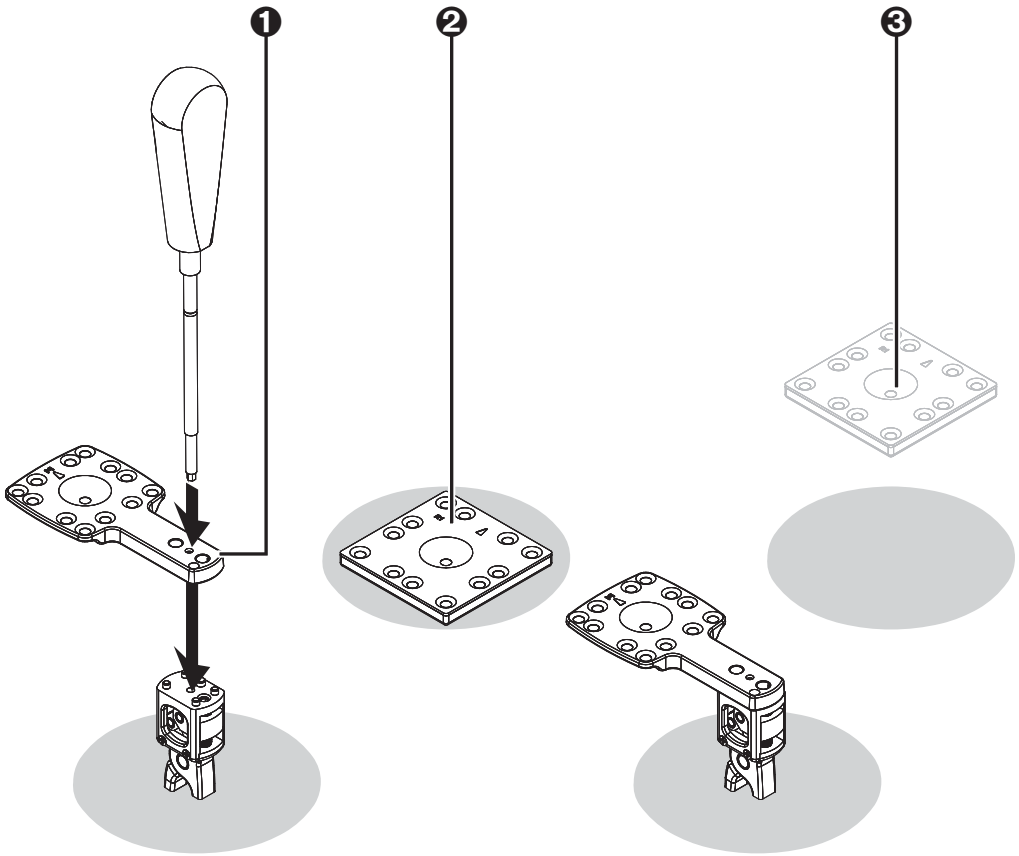
X-Marker Registration

Use X-Marker registration when Z-Marker registration is not suitable.

Two markers are used for X-Marker registration. They are placed as follows:

- The X-Marker is placed on the patient in the area that will be operated on and scanned.
- The patient marker is placed on the patient, connected to the patient clamp.

Figure 14: X-Marker Registration



❶ Attach the patient marker to the patient clamp with the allen screwdriver. The patient marker should point away from the area to be operated on.
❷ Secure the registration marker on the patient's back in the area of the 3D scan using the provided double-sided adhesive.

Note: The registration marker should be attached on a sterile cloth or Ioban drape to ensure non-direct contact between the marker and the patient's skin.

❸ Initiate an intraoperative 3D scan of the area, verifying that the registration marker is included in the scan.
❹ X-Marker registration is completed after the intraoperative scan is loaded in the new study. Refer to *Completing X-Marker Registration* (page A-1).

7. Spine Surgery with the XVISION-SPINE System

When all preprocess tasks have been completed continue with preparing the surgical procedure at the computer where the **INTERFACE SOFTWARE** is installed.

7.1. New Study

Use the **New Study** screen to finalize all procedures for the surgical procedure.

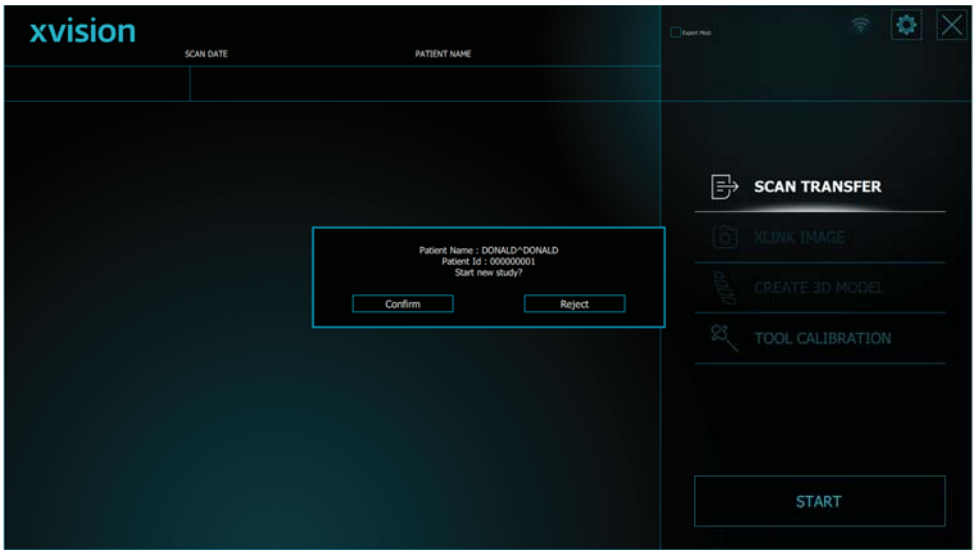
Typically, at the end of the intraoperative scan, 3D data is sent directly to the computer where the Interface Software is installed. Where DICOM is not available, data can be loaded via a portable USB drive.

Confirm that you want to delete saved data to continue.

Note: Old data is never saved.

The intraoperative scan that is waiting in the queue, or that you have selected from a portable USB drive, begins to load. The progress can be seen in the number of slices shown as completed in the top right corner of the screen.

Figure 15: Confirm New Study



When the scan has been loaded confirm that this is the correct scan for the patient.

7.2. Create 3D Model

With a completed registration tap **Create 3D Model**.

Note: See *Completing X-Marker Registration* on page A-1 if you have used the X-Marker registration method.

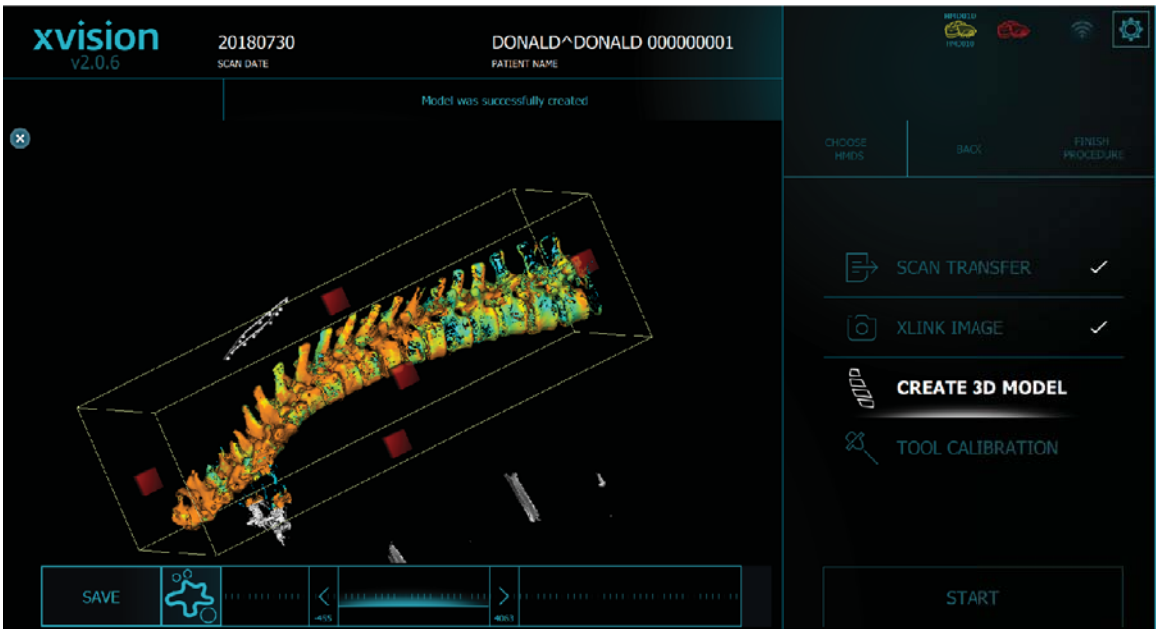
Figure 16: Create 3D Model

Note: For touch screens, the technician uses standard pinch and swipe gestures to manipulate the model (A), including pan, zoom in/out, and rotate rendered data.

The window level (B) is used to set threshholds for the image to eliminate everything but bone tissue.

When the image is satisfactory tap **Create Model** (C).

Figure 17: Create Mesh



The bounding box around the mesh can be adjusted to remove artifacts by rotating it and then pressing one of the orange handles to crop out unneeded data.

When the mesh shows the spinous process is clearly as possible tap **Save**. The save process may take several minutes. Then press **Start**.

7.3. Beginning the Surgical Procedure

One **Start** has been pressed, the surgeon, with the aid of a technician at the the computer where the **INTERFACE SOFTWARE** is installed, has flexibility in how the area is viewed.

Warning: While wearing the **HEADSET**, if you feel dizziness, headache or nausea remove the **HEADSET** and rest. Contact Augmedics service.

Warning: Do not to use the **XVISION-SPINE** system if the image freezes, disappears or keeps flickering for more than several seconds.

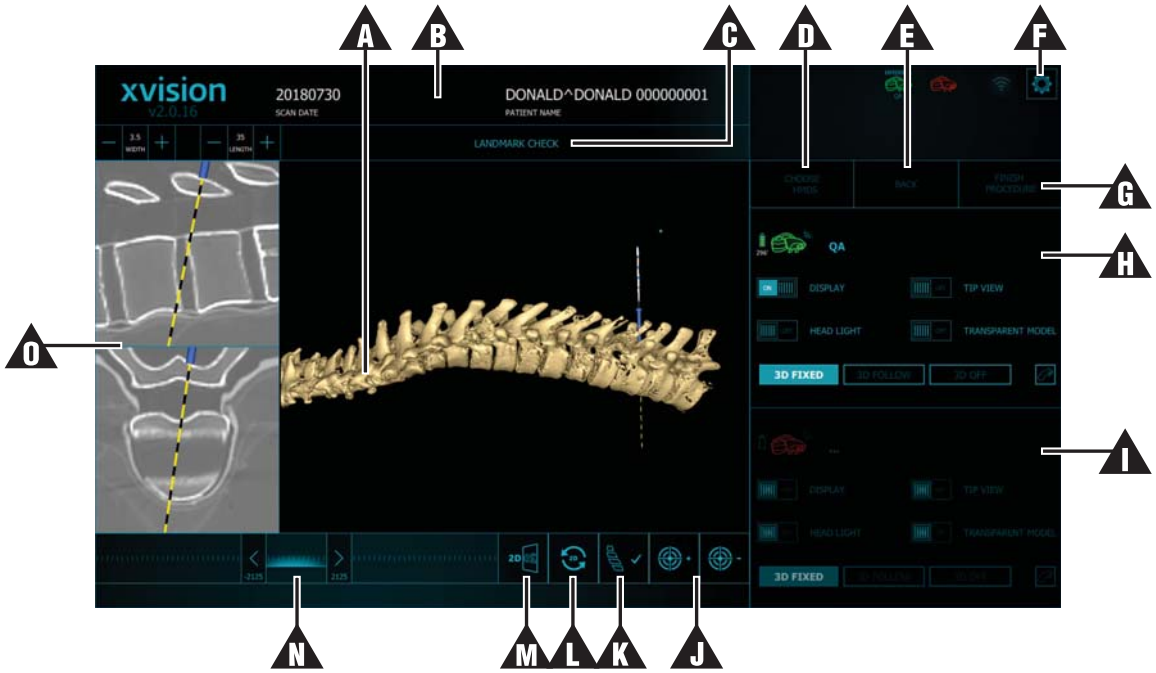
Warning: In case of observed delay in image, do not use the **XVISION-SPINE** system.

Note: Make sure that the registration marker is kept in place between the CT scan and the **HEADSET** image.

Note: During the surgical procedure the **HEADSET** should remain between 30 cm and 70 cm above the tracked instruments.

Note: Return the **HEADSET** image view by moving the head when you are out of working limits.

Figure 18: Main Screen



Area	Name	Notes
A	3D Mesh display	Use this area to manipulate the image
B	Current patient information	
C	Notification area	
D	Choose **HEADSET**	
E	Back	

Area	Name	Notes
F	Setup menu	
G	Finish procedure	
H	**HEADSET** 1 Controls	*Headset Controls* (page 7-6)
I	**HEADSET** 2 Controls	For procedures when two **HEADSET**s are used
J	Virtual trajectory guide controls	*Virtual Trajectory Guide* (page 7-12)
K	Landmark check	*Landmark Check* (page 7-11)
L	Rotate image control	
M	2D Mirror	
N	Window level threshold controls	
O	2D Slice display	This area is visible only after *Tool Verification* (page 7-10)

7.3.1. Headset Controls

The technician in the operating room uses the controls below according to the verbal instructions of the surgeon during the procedure.

Warning: If the **HEADSET** fails a message appears on the **HEADSET** and the system monitor. In this case use a different **HEADSET**.

Warning: In case of loss of image in either or both eyes use a different **HEADSET**.

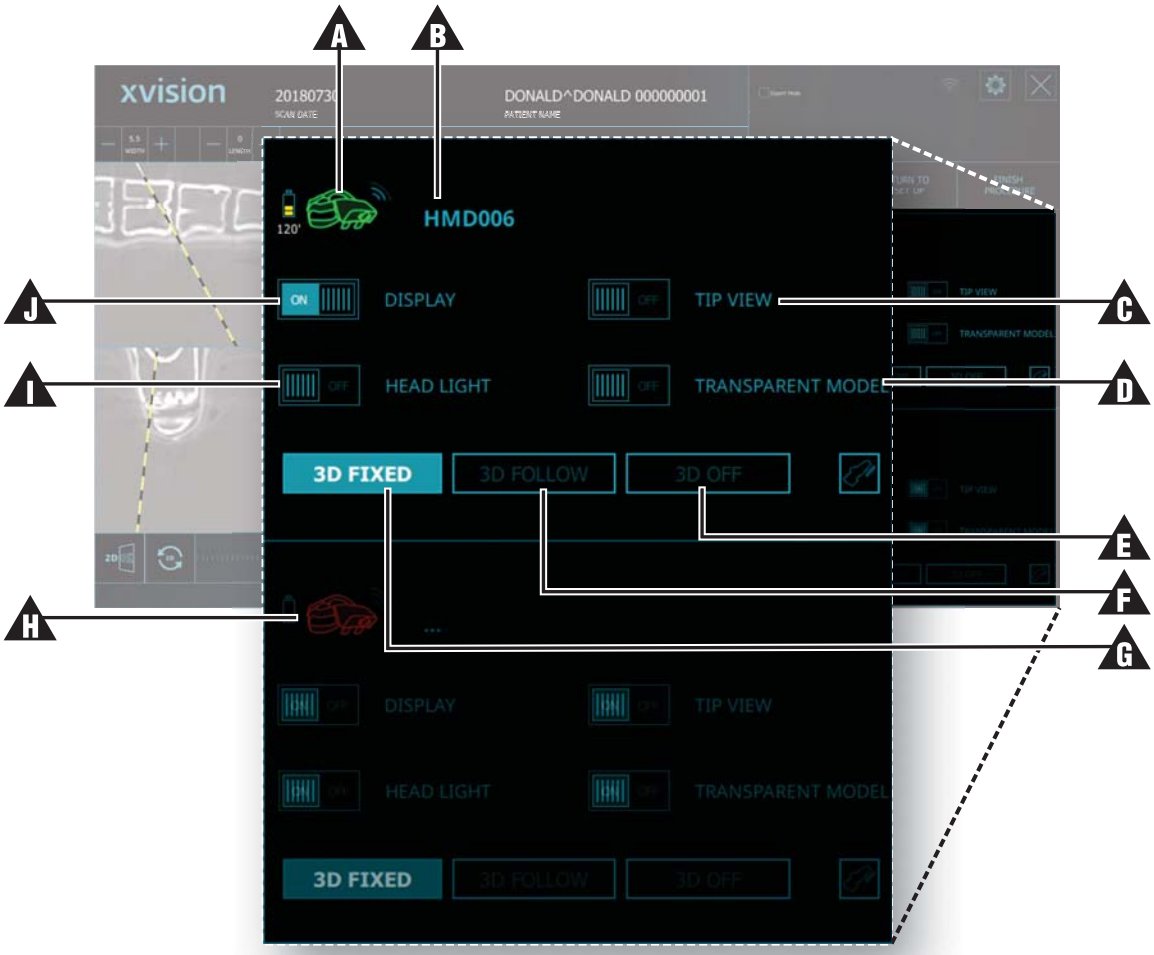
Warning: In case of detected failure or an insecure feeling, or when reality and projected display are not aligned, use a different **HEADSET**.

Warning: If the image freezes, disappears or flickers for more than several seconds use a different **HEADSET**.

Note: Check lenses and (optional) LCD before starting the procedure. If the lenses are dirty or the image is blurry use a different **HEADSET**.

See *Footswitch Controls* on page 7-9 for controls available to the surgeon using the Footswitch.

Figure 19: Headset Controls



Area	Name	Notes
A	**HEADSET** status	• Green: Located and initiated • Yellow: Waiting for data or initiating data
B	**HEADSET** device name	See *Headset Pairing* on page 5-3 for more information
C	Tip View	Cuts/removes layers according to where the tip of the surgical instrument is located
D	Transparent Model	Available only on **HEADSET**
E	3D Off	Slice view only
F	3D Follow	Region interest follows the tool
G	3D Fixed	Show fixed 3D and 2D (slice) displays (according to **HEADSET** movement)

Area	Name	Notes
H	Inactive **HEADSET**	Up to two **HEADSET**can be used during a single procedure
I	Head Light	Toggle **HEADSET** light off and on
J	Display	Toggle **HEADSET** display off and on

7.3.2. Footswitch Controls

The surgeon can control the following **XVISION-SPINE** software functions using the Footswitch.

Figure 20: Footswitch Controls

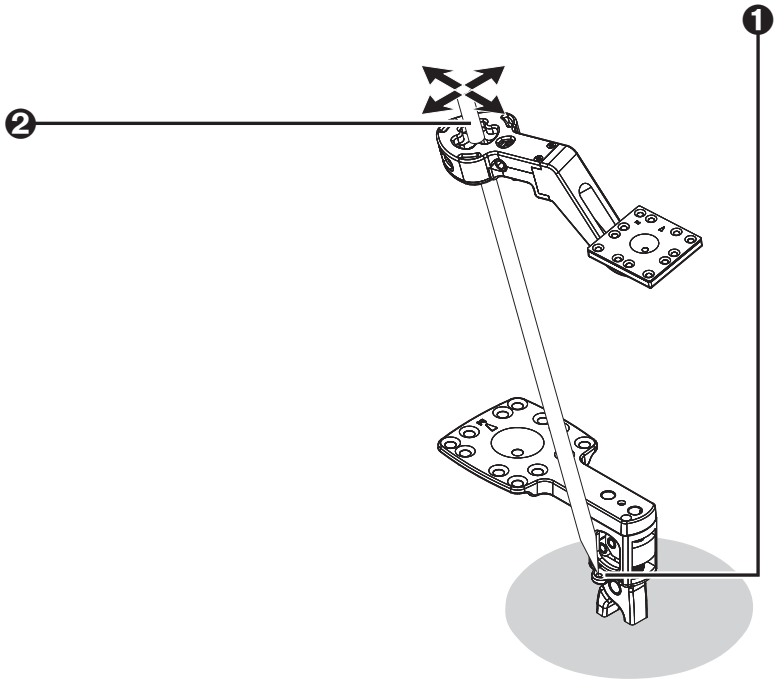
Area	Name	Notes
A	Left switch	Toggle Headset display off and on
B	Center switch	Cycle between 3D Fixed, 3D Follow, 3D Off
C	Right switch	Place virtual trajectory guide. See *Virtual Trajectory Guide* on page 7-12 for more information.

7.4. Tool Verification

When a new tool enters the area the system requests tool verification. The surgeon sees a red notice on the **HEADSET**.

Note: Tool verification is required for the screwdriver every time a new screw is attached to the tool.

Figure 21: Tool Verification



❶ Touch the tip of the surgical instrument to the v-point on the body clamp.
❷ Swivel the surgical instrument, keeping the tip on the v-point.

When verification has been completed the Headset and the computer where the **INTERFACE SOFTWARE** is installed indicate **Tool OK**.

Note: If the patient marker is to be moved to the other side, touch the tool to the verification point.

7.5. Landmark Check

When the surgeon has verified the first tool a landmark check is done to verify that the **XVISION-SPINE** system is correctly interpreting the location of the tool tip.

Figure 22: Landmark Check

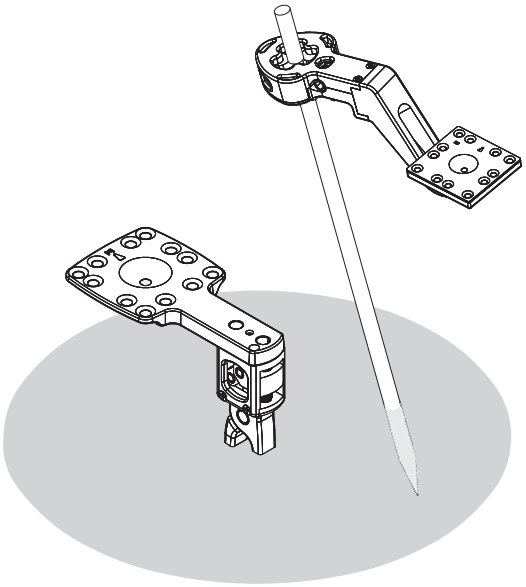
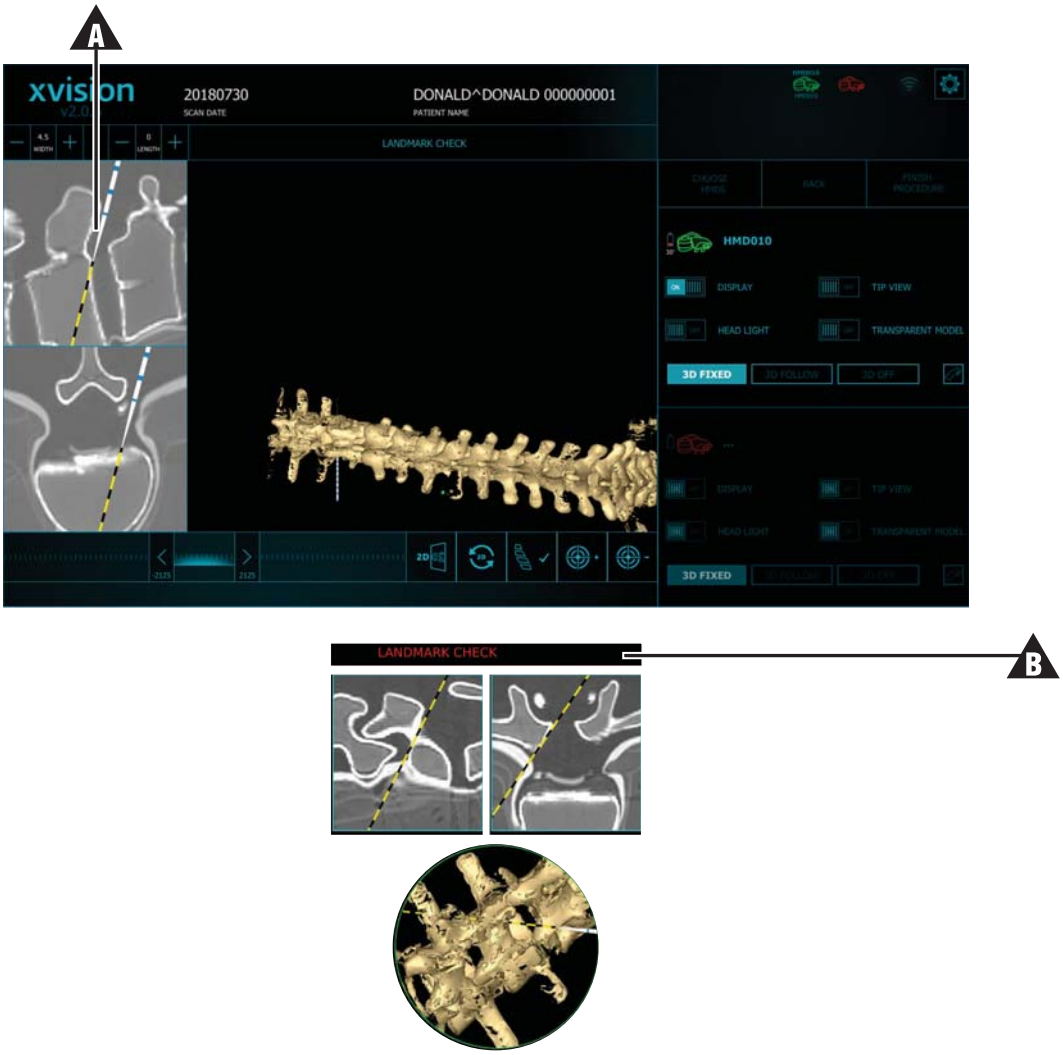


Figure 23: Landmark Check Screen



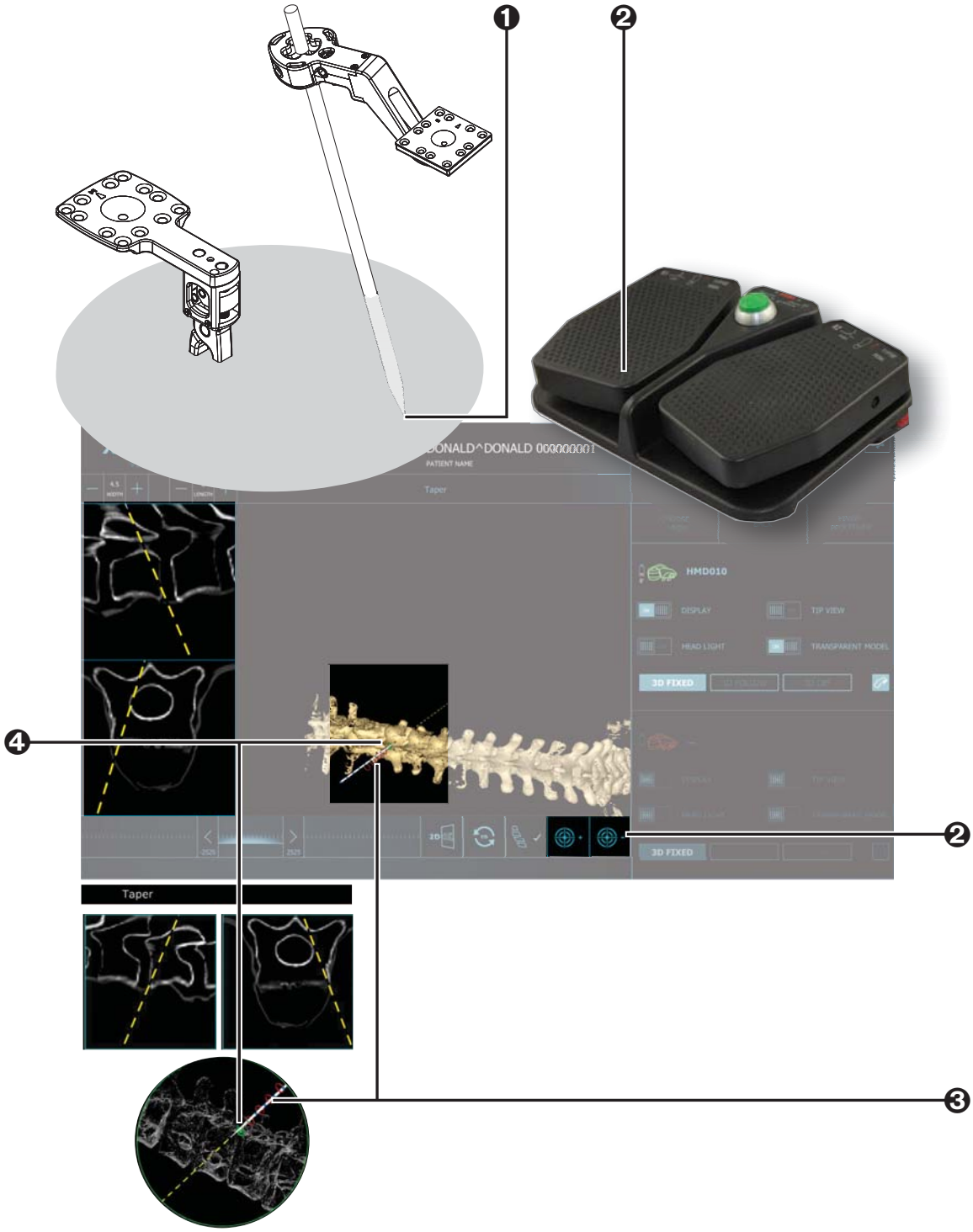
Touch a known anatomical spot, such as a particular vertebra, or a part of the clamp, with the tip of the tool. If the physical location of the instrument and the display of the **XVISION-SPINE** monitor (A) and the **HEADSET** (B) match, the surgeon instructs the technician to tap **Verified**.

Note: The landmark check is required only on the first tool after verification.

7.6. Virtual Trajectory Guide

During the procedure the surgeon may want to prepare a trajectory for a tool, as follows:

Figure 24: Virtual Trajectory Guide



❶ Using the navigation tools, the surgeon touches the tip of the surgical instrument on the bone.
❷ The surgeon then presses the left pedal, or instructs the technician to tap the **Target plus** button.
❸ Red cross hairs appear on the **HEADSET** and computer displays, marking the target location.

❹ At the same time, green cross hairs mark the entrance location, about 5 cm up the length of the surgical tool.

The surgeon now has a virtual trajectory guide that can be used to insert another surgical tool at the same location.

The virtual trajectory guide interface is also used to put a screw in place; tap **Target Plus** at the end of the insertion to leave a virtual screw in the display.

To remove a virtual trajectory guide:

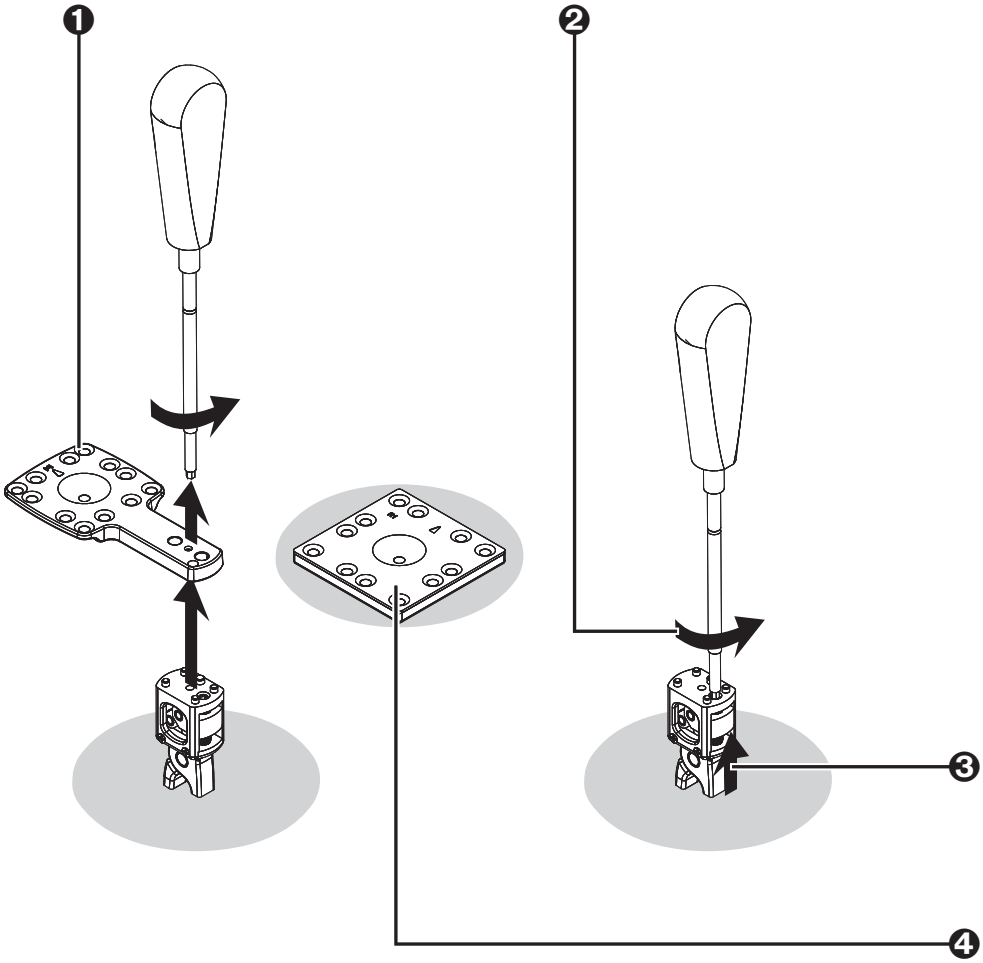
- Double-click the target, or
- Move the tool inside one of the red circular guides and tap the **Target minus** button.

Note: Virtual trajectory guides can only be removed by the technician at the computer monitor.

7.7. Ending an xvision-Spine Procedure

At the end of the **XVS** portion of the surgical procedure follow the steps below:

Figure 25: Ending the **XVS** Procedure



1. Remove the patient marker from the patient clamp using the allen screwdriver and set it aside for cleaning and sterilization.
2. Loosen the patient clamp using the allen screwdriver and set it aside for cleaning and sterilization.
3. Remove the patient clamp and set it aside for cleaning and sterilization.
4. Remove surgical tools from their Universal Tool Adaptors and send them for cleaning and sterilization.

Note: For procedures that used the Z-Marker registration procedure, send the Z-Marker for cleaning and sterilization.

5. Tap **Finish Procedure** in the **INTERFACE SOFTWARE**.
6. Power down the **HEADSET**.
7. Remove the **HEADSET**, taking care to touch only the plastic parts.
8. Remove the the **HEADSET** battery and place it in the charging station.
9. Clean the **HEADSET** with wipes and return it to its case.

10. Dispose of all components from the Single Use Sterile Kit (patient markers, tool markers, and X-Marker registration marker).

8. Cleaning Reusable Components

Follow the procedure below to clean the reusable components of the **XVISION-SPINE** system:

- Patient clamps (Patient Clamp—Straight, Patient Clamp—Arc)
- Universal Tool Adaptors
- Allen screwdriver
- Z-Markers

All reusable components must be thoroughly cleaned and sterilized before initial use and after each subsequent use.

None of the reusable components in the system require disassembly prior to cleaning.

Caution: Do not use solvents, lubricants, or other chemicals unless otherwise specified.

Note: Whenever possible, do not allow blood, debris, or body fluids to dry on instruments. For best results, and to prolong the life of the reusable components, process immediately after use.

8.1. Automatic Cleaning

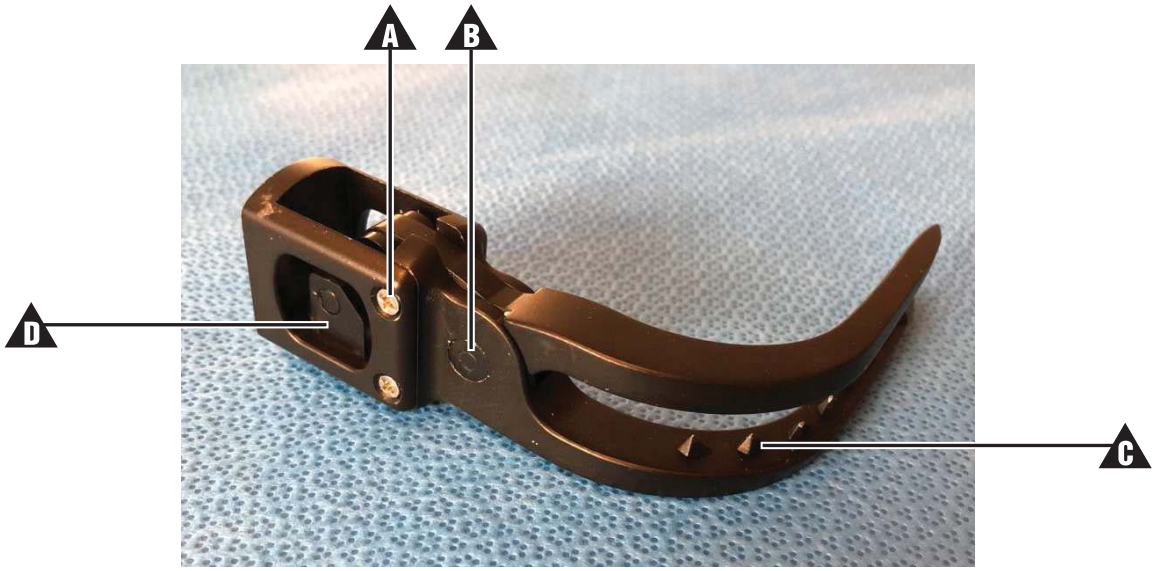
Follow the pre-cleaning procedure below:

1. Rinse the devices under cold running utility water to remove gross soiling.

Note: Water quality is specified in AAMI TIR34: 2014.

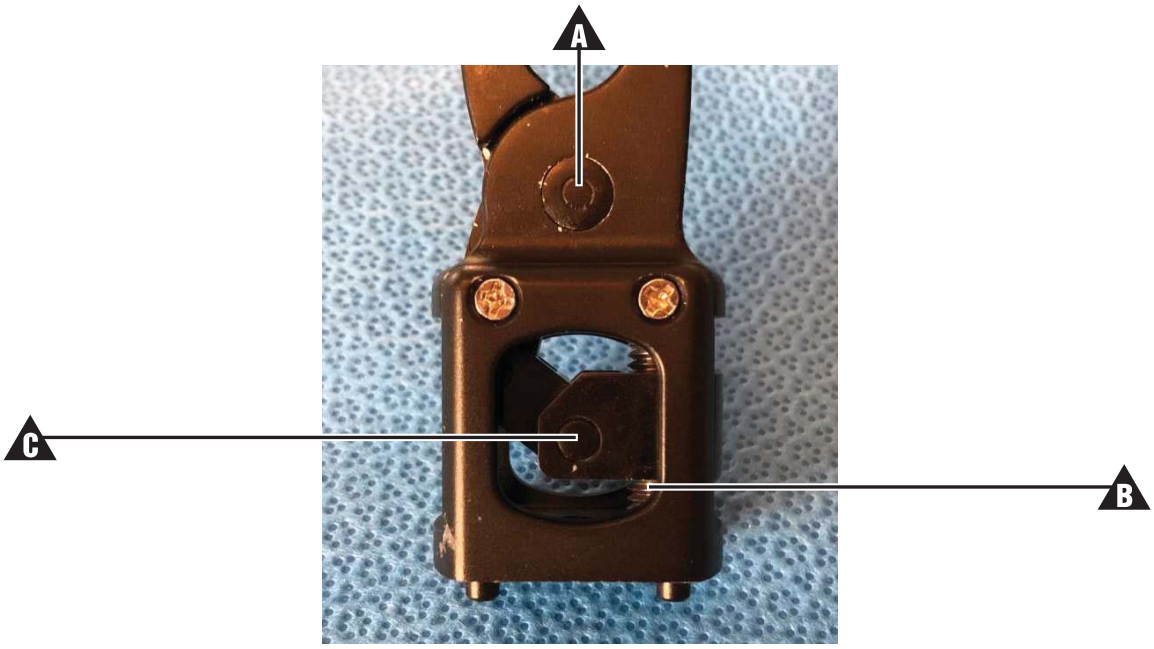
2. While rinsing, use a soft-bristled brush to aid in the removal of soiling, focusing on all hard-to-reach places. See the following figures for more information.
3. Prepare a detergent bath of Valsure® Enzymatic Cleaner at 8 mL per liter (1 oz per gallon) or Neodisher® Mediclean Forte Detergent at 5 mL per liter of lukewarm utility water in an ultrasonic unit.
4. Immerse the devices in the detergent bath and sonicate for a minimum of two minutes.
5. Transfer the devices onto a rack accessory contained inside the washer for processing.

Figure 26: Cleaning Patient Clamp Arc



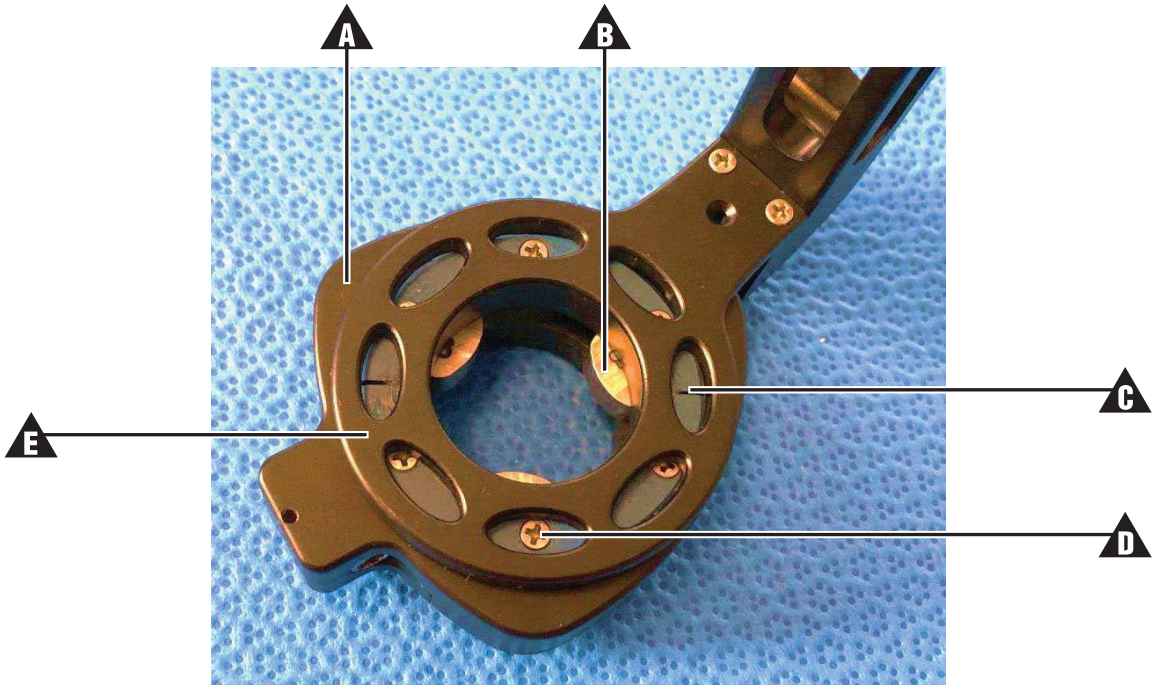
A Cage screw
B Clamp pin
C Arm teeth
D Clamp hinge assembly

Figure 27: Cleaning Patient Clamp Straight



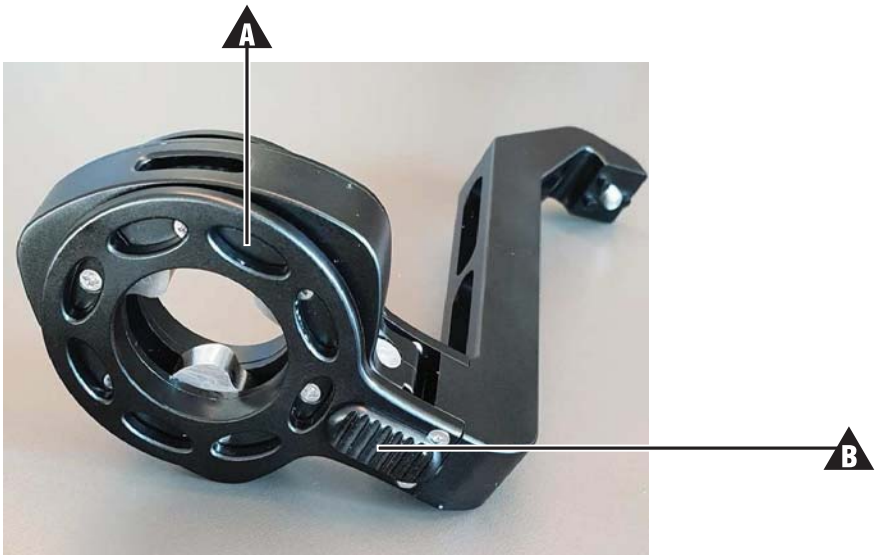
A Clamp pin
B Set screw
C Hinge pin

Figure 28: Cleaning Universal Tool Adaptor



A Adaptor body
B Adaptor piston
C Adaptor gear ring
D Adaptor captive screw
E Adaptor plate

Figure 29: Cleaning Swivel Universal Tool Adaptor



A Adaptor gear ring
B Adaptor button

Use the following washer cycle.

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration (if applicable)
Pre-rinse 1	02:00	Cold utility water	N/A
Wash 1	02:00	43 °C utility water	Valsure® Neutral Detergent (US) at 2.0 mL/L or Neodisher® Mediclean Forte (EU) at 2.0 mL/L
Rinse 1	1:00	Cold utility water	N/A
Pure Water Rinse	1:00	43 °C criticall water	N/A
Dry Time	07:00	115 °C	N/A

8.2. Steam Sterilization

Sterilize the devices per the parameters below. Two cycles are possible.

Prior to the sterilization cycle, the tray of devices should be individually wrapped in two layers of 1-ply polypropylene wrap (Halyard Health H600 or equivalent).

Note: The hospital is responsible for cleaning and autoclave sterilization of all resusable components.

Steam Sterilization Parameter	Cycle # 1	Cycle # 2
Cycle Type	Pre-vacuum	Pre-vacuum
Preconditioning Pulses	4	4
Temperature	132 °C	134 °C
Exposure time	4 minutes	3 minutes
Dry time	30 minutes	30 minutes

9. Maintenance and Service

The **XVISION-SPINE** (**XVS**) system requires yearly maintenance. System calibration and updates are provided as required by service personnel. Service should only be provided by an authorized Augmedics Ltd representative.

10. Troubleshooting

Message Area Warnings

Message	Result/Reason	Solution	Notes
From Monitor			
MULTIPLE TOOLS	The system has detected more than one tool in the operating area (field of view)	Remove the tool that is not in use.	No image displayed on **HEADSET**
NO TOOL	The system has detected that no tool or patient in the operating area.		No image displayed on **HEADSET**
NO PATIENT MARKER			
DISPLAY OFF			No image displayed on **HEADSET**
SYNCING DATA	System is initializing		No image displayed on **HEADSET**
LOW BATTERY	Battery Indicator icon is yellow or red	Change battery	No image displayed on **HEADSET**
Model building closed without saving mesh file			
Monitor Is Not Connected	The **HEADSET** has detected that the monitor software is not running		No image displayed on **HEADSET**
XLINK			
Register marker or patient marker is missing	The system cannot detect one of the markers. Patient Registration Failed	• The markers have not been placed on the patient • The **HEADSET** is not aimed at them • The **HEADSET** is malfunctioning	
Recognized more than two markers		Remove one marker from the operating area	
DicomRead Failed for : %s" % path	There is a problem reading the scan	Try reading again or recopy data onto the USB	Contact service if problem persists
Do not touch the markers during Xlink image process			
Registration marker was not detected in scan!	There is a problem with the patient scan	Verify that the registration marker is visible in the scan (using external software on the scanner). Repeat the scan.	Contact service if problem persists
Registration failed			

Message Area Warnings (continued)

Message	Result/Reason	Solution	Notes
Tool Calibration			
{} HAS ALREADY BEEN CALIBRATED!			
{} HAS ALREADY BEEN CALIBRATED! {}% completed			
{} HAS ALREADY BEEN CALIBRATED! {}% completed Move the tool wider!			
Recognized more than two markers		One marker/tool needs to be removed from the operating area	Tool cannot be calibrated
Tool marker and patient marker are missing	Tool cannot be calibrated The system cannot detect the marker.	• The marker is not attached • The **HEADSET** is not aimed at the operating area • There is a disturbance in the line of sight from the **HEADSET** to the marker	Contact service if problem persists
Tool marker is missing			
Patient marker is missing			
Calibration failed - You did not move the tool wide enough	Tool calibration failed for one of the reasons indicated	Follow instructions and repeat the process	If this problem persists with multiple tools contact service
Calibration result is not approved. Please note that the tool is placed on the calibration point and try again			
Calibration result is not approved. Please try again			
Monitor Is Not Connected	No tracking display on computer monitor	• Check the connection the communication box • Check the power to the communication box • Restart the Headset and software	Contact service if problem persists
No adapter contains router ip found	Cannot configure DICOM connection	There is a problem with configuring the system DICOM connection	Contact service if problem persists
General Errors			
Blue screen on computer monitor		Make sure all cables are connected properly.	If all cables are connected properly, shut down the system and contact service.
Error message: Sbit failed two times	Hardware failure is detected in the **HEADSET**.	Use another **HEADSET**.	Contact service if problem persists
Error message: Free RAM is below 2[GB]	Hard disk is full.		Contact service

Message Area Warnings (continued)

Message	Result/Reason	Solution	Notes
Blurry or no image display	Lens and LCD are not clean	Gently wipe them using a lint-free soft cloth	Contact service if problem persists
	Lens and/or LCD are scratched	Use another **HEADSET**.	
Projected display and reality are mixed	Insecure feeling due to mixed display of projected display and reality	Use another **HEADSET**.	Contact service if problem persists
No indication of virtual tool on computer monitor		Move your head slowly downwards or upwards until the virtual tool is displayed again.	Shut down the system and contact service if problem persists
		Use another **HEADSET**.	
Displayed Image is frozen	Tracking is lost	Verify that all cables are connected correctly. If all connected, try using a different **HEADSET**.	Shut down the system and contact service if problem persists
Error Message: Registration Failed		Capture a new set of images with the **HEADSET**. Verify both the Registration Marker and the Patient Marker are within the required FOV. Load images and press “Registration” again.	Shut down the system and contact service if problem persists

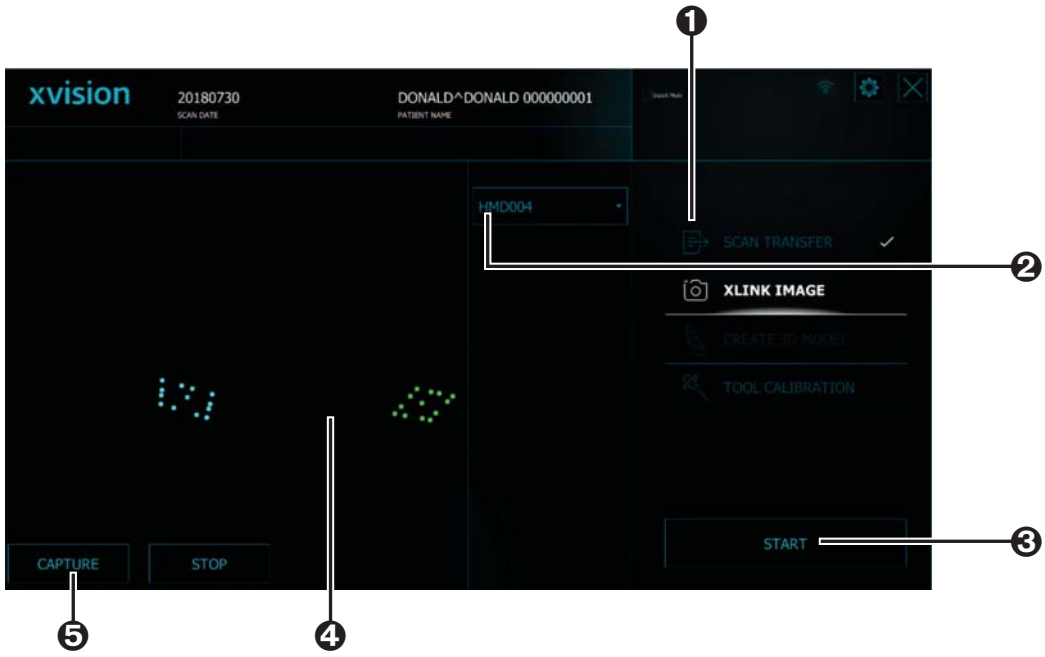
Appendices

The material in these appendices include important information about your **XVISION-SPINE** system.

Appendix A: Completing X-Marker Registration

To complete X-Marker patient registration first follow the procedures in *New Study* (page 7-1). When you are done continue as follows.

Figure 30: Completing X-Marker Registration



❶ Transfer the captured images from the scanner to **XVS** (using DICOM or USB).
❷ Select a device to complete registration from the dropdown menu, which includes up to two available **HEADSET**s.
❸ The **INTERFACE SOFTWARE** prompts the user to capture an X-Marker image using the **HEADSET**. Press **Start**.

> **Note:** X-Marker image capture should be done during the same breathhold as the 3D scan.

❹ Using the **HEADSET**, the surgeon looks at both markers until they appear on the screen.
❺ The technician taps **Capture**. When the registration is complete the system indicates success.

When this is done continue with *Create 3D Model* (page 7-2).

Appendix B: System Specifications

The specifications listed apply to system operation under typical conditions:

Environmental Conditions	
Operating Temperature	Between 10 °C and 30 °C
Electrical Safety	
Input Voltage	Battery operated 9-12 V
System Classifications	
Electrical Safety Classification (IEC 60601-1:2005/A1:2012)	Class I, continuous operation
Electromagnetic Emissions Compatibility, IEC 60601-1-2	Class A
HEADSET Water Ingress Classification	IPX0 (not protected)
HEADSET Rx/Tx	802.11 b/g/n
HEADSET Frequency Range	2412.0 - 2472.0 MHz
HEADSET Bandwidth	20 MHz; ERP: 21.83 mW
General	
Reusable Components	
Patient Clamp	Biocompatible (compliant with ISO 10993-1); Steam sterilized
Tool Marker Holder	Steam sterilized
Z-Marker	Steam sterilized
Sterile, Single Use Components	
Patient Marker	Dimensions: 64 mm X 64 mm X 8 mm, gamma sterilized
Tool Marker	Dimensions: 48 mm X 48 mm X 18 mm, gamma sterilized
Registration Marker	Dimensions: 80 mm X 80 mm X 18 mm, gamma sterilized

Appendix C: Waste Electrical and Electronic Equipment

In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual procedure and recovery at an approved recycling facility.

By returning waste electrical and electronic equipment via the correct segregated disposal channel, users can ensure the environmentally sound procedure and disposal of the waste equipment, thereby reducing the potential for any environmental or health risks that could arise as a result of incorrect disposal.

Appendix D: Universal Tool Adaptors

The **XVISION-SPINE** system includes universal tool adaptors of two types that are suitable for most surgical instruments.

Tool Name	Diameter	Leg Height
Swivel tool adapter swivel 8 down 35	2 mm-20 mm	+25, -35, -120
Fixed tool adapter 5 down 35	2 mm-20 mm	+25, -35, -120

Augmedics

xvision