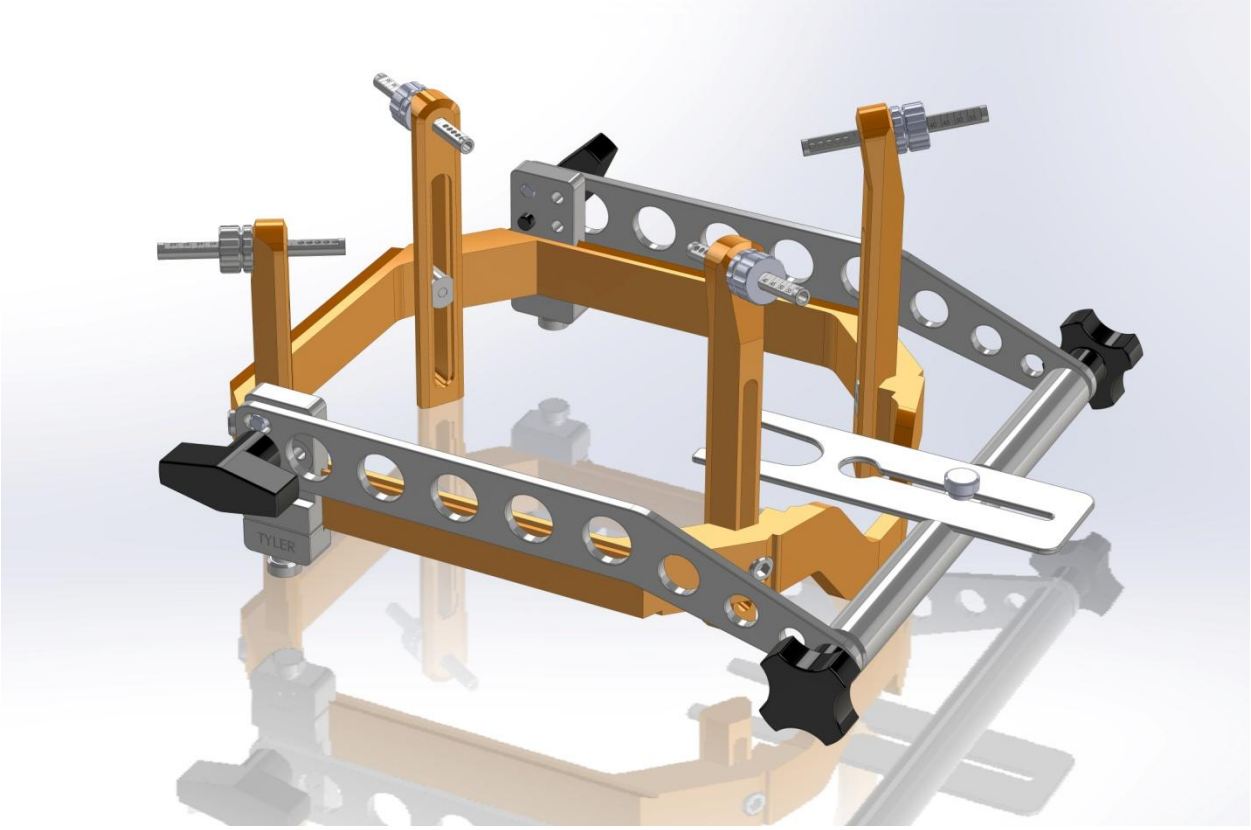
Tyler Alignment & Calibration System

For the Leksell Stereotactic Frame

Instructions for Use



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Leksell Stereotactic Neurosurgery

Stereotactic Radiosurgery (SRS) involves the destruction of selected tissue in the brain or spine using ionizing radiation, rather than excision using standard surgical procedures. The technique was pioneered by the Swedish neurosurgeon Lars Leksell in 1949, and introduced clinically in 1984.

The term "stereotactic" refers to the implementation of a three-dimensional coordinate system to permit a direct correlation between the virtual images obtained through diagnostic procedures such as magnetic resonance imaging (MRI) or computed tomography (CT) and the actual target in the patient's brain. The development of the Leksell stereotactic frame has made targeting extremely precise, permitting the inactivation or eradication of brain lesions with minimal effect on the surrounding normal tissue.

The Leksell stereotactic system consists of an aluminum frame that is securely affixed to the patient's skull with either three or four retaining screws. It both immobilizes the skull and serves as a reference frame by which the diagnostic images and the actual tumor are superimposed. Once attached, the frame provides unprecedented precision for radiosurgery in the gamma knife's isocenter.

As superb as the positioning of the Leksell fixation frame is inside the gamma knife, a major difficulty lies in properly affixing it to the patient's skull. It is a cumbersome process, usually involving several people, trial and error in determining injection and attachment points, and a great deal of time and effort on the part of surgical support staff.

The Tyler Alignment & Calibration System

The Tyler Alignment and Calibration System addresses these shortcomings: the purpose of the device is to streamline the fixation process for the Leksell frame, to minimize discomfort for the patient, and to reduce the time and staff required attaching the stereotactic frame. It consists of two parts – (1) the alignment frame, and (2) calibrated needle guides.

(1) The upper jaw is part of the skull, and the lower jaw is attached to it with some of the strongest muscles in the human body. The jaw, then, can serve both as a reference position and a clamp to position the fixation frame. The Tyler alignment frame is connected to the Leksell fixation frame by means of adjustable dovetail clamps, and through a series of flexible joints in the alignment frame, a disposable bite plate is incorporated into the Leksell frame. The combined fixation frame and alignment frame is placed over the head and the patient is instructed to bite down firmly on the bite plate. The alignment frame is then adjusted with the flexible joints in a fluid configuration, and the joints of the frame then immobilized at the appropriate positions by turning each of four knobs. This locks the frame firmly in place, so it is maintained in the proper position regardless of whether the patient moves his head from this point forward.

(2) The hollow needle guides are then pushed gently into firm contact with the skin. Anesthetic is injected through the needle guides into the precise positions at which the retaining screws subsequently will be placed in the skull. At the same time the correct length of retaining screw for each position is easily determined by reading the scale in the needle calibration assemblies. The calibration guides are then removed and the appropriate retaining screws inserted into the threaded inserts and tightened securely. Finally, the alignment frame is removed, loosening the two thumb screws by which it is attached through dovetail clamps to the fixation frame and sliding it forward, away from the patient's head and the fixation frame.

Preparing the Tyler Alignment Frame

With the exception of the bite plate (an individually packaged, single use item) and the calibrated needle guides, there is no need to sterilize the calibration system, although a protocol is provided for those treatment centers that wish to do so.

Figure 1

The alignment frame in its assembled state is shown in Figure 1.

Cleaning the Alignment Frame:

- Under normal circumstances it should not be necessary to disassemble the frame into its component parts. The only conditions requiring disassembly are:
    - Replacement of a damaged component (see Section A), or
    - Contamination of the frame with blood or body tissues (see Section B)

- Hand wash the assembled frame thoroughly in a mild detergent with a pH of 6 to 8.
- Rinse several times in deionized water to remove all traces of detergent
- Dry the frame with a clean, soft, lint-free cloth

Drying and Wrapping Recommendations:

The Tyler Alignment Frame may be sterilized if desired, although this is not necessary in the context of normal use as an aid for positioning the Leksell fixation frame. If sterilizing:

- Ensure that the assembled frame is completely dry before sterilization
- Inspect all parts for visible soil or contamination
- Prepare the frame for autoclaving by placing it into the sterilization box provided and wrap the sterilization box in cloths intended for autoclaving

Sterilization:

Cycle parameters for prevacuum or intermittent vacuum steam sterilization:

- Holding (exposure) temperature of 132°C (270°F)
- Holding (exposure) time of 10 minutes
- Drying time (minimum, in chamber) of 30 minutes

Cleaning the Needle Guide Assemblies:

A calibrated needle guide assembly is shown in Figure 2. Typically, a set of 4 of these is required for each patient fixation. These are reusable components and must be cleaned and sterilized prior to use.

- Disassemble and hand wash the aluminum needle guides and collets thoroughly in a mild detergent with a pH of 6 to 8.
- Rinse several times in deionized water to remove all traces of detergent
- Dry the collet components and calibrated guide tube with a clean, soft, lint-free cloth, and reassemble (see Figure 11)

Figure 2

Packaging Recommendations:

- Package the fully assembled needle guides individually in an appropriately-sized self-sealing sterilization envelope
- Place the envelopes in a suitable container or cloths intended for autoclaving

Sterilization:

Cycle parameters for prevacuum or intermittent vacuum steam sterilization:

- Holding (exposure) temperature of 132°C (270°F)
- Holding (exposure) time of 10 minutes
- Drying time (minimum, in chamber) of 30 minutes

Attachment of the Alignment Frame to the Leksell Fixation Frame

Position the clean, dry (and optionally sterile) alignment frame on a flat surface in the prep room

- Gently tighten the 4 black adjustment knobs so that the frame is aligned approximately as shown in Figure 1.
- Loosen, by turning counter clockwise approximately three full turns, the 2 thumbscrews on the undersides of the dovetail clamps
- Position the top V of each clamp at the anterior end of the Leksell frame's dovetail side rails
- Holding onto the front bar of the alignment frame, gently slide it towards the rear of the side rails, stopping when the anterior edges of the dovetail clamps are parallel at a position of approximately 50 on the engraved scales of the side rails
- Firmly tighten the thumbscrews to lock the alignment frame to the fixation frame, and test to ensure that the clamps will not slide forward or backward
- Remove an assembled needle guide assembly (collet and calibrated guide tube) from its sterile envelope and slide the guide tube inside the collet until the proximal end (the end with the holes) is contained completely inside the collet (see Figure 3) and screw the collet into the plastic insert at the top of a Leksell fixation post

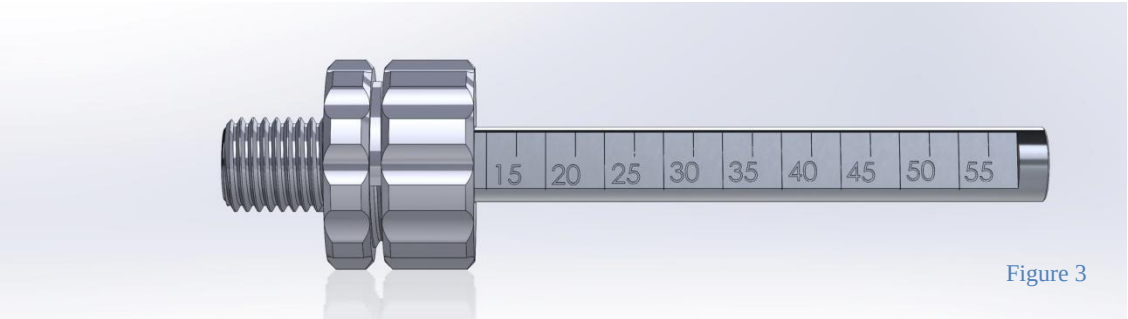

Figure 3

- Repeat with the other three needle guide assemblies, to completely populate all the fixation posts of the Leksell frame
- At this point the combined frame assembly should appear as shown in Figure 4. and is ready to be positioned on the patient

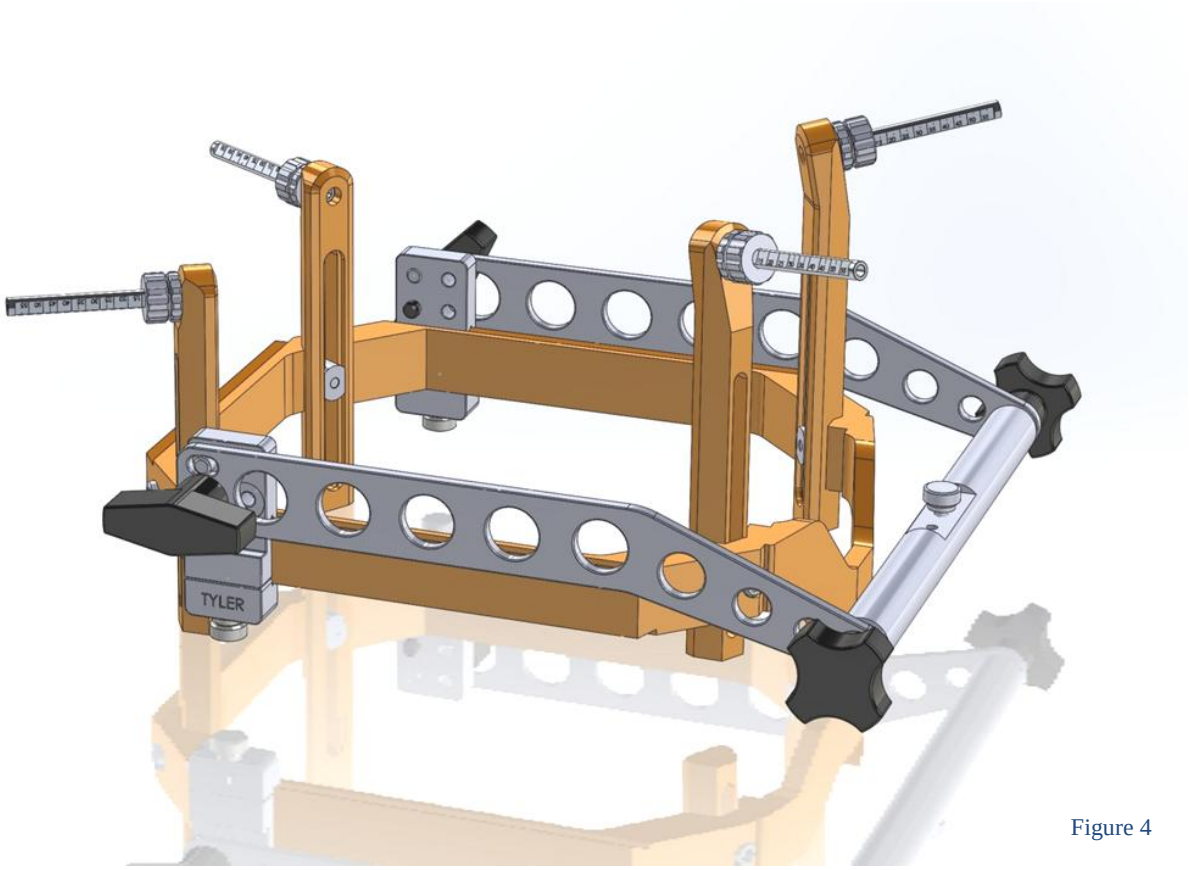

Figure 4

Instructions for Fixation of the Frame to the Patient

- Open the packaging of a single bite plate and set it aside.
- Adjust the four black knobs of the alignment frame so that the movable joints of the frame are firmly immobilized. The side arms and the front bar should be fixed in place, but able to be moved with moderate pressure. The flat plane of the front bar that holds the bite plate should be parallel to the plane of the Leksell frame.
- Grasp the combined alignment/fixation frame by the sides and lower it over the patient's head, bringing it to rest just below the ear.
- Install the bite plate onto the front bar of the alignment frame by slipping the keyhole in the bite plate over the head of the thumbscrew on the bar.
- Instruct the patient to open his mouth and slide the bite plate gently backward. When the patient's head is approximately centered in the Leksell frame and the cushioned portion of the bite plate is fully in his mouth, instruct the patient to bite down slowly but firmly on the plate (Figs. 5 and 6).
- Adjust the position of the frame in the preferred dorsal/ventral position by allowing the bite plate to slide, and then tighten the thumbscrew firmly to capture the bite plate against the front bar.
- NOTE: In the event of an emergency (anxiety, choking, airway obstruction) the bite plate can be removed in a matter of seconds by loosening the thumbscrew and sliding the plate out of the patient's mouth, then removing it entirely by slipping it off of the thumbscrew through the keyhole in a reverse of the procedure by which it was attached to the front bar.

- Adjust the angle of the alignment frame's side arms until the Leksell frame is in the desired position with respect to the patient's head.
- Compensate for any tilt in the angle of the side arms by adjusting the rotation of the front bar that holds the bite plate, so the patient is comfortable and the frame is properly positioned.
- Firmly tighten the two-arm knobs to lock the side arms in position, and then the four-arm knobs to lock the bite plate in position.
- At this point, as long as the patient keeps the bite plate firmly clamped in his mouth, he should be able to move his head without changing the relative position of the fixation frame.

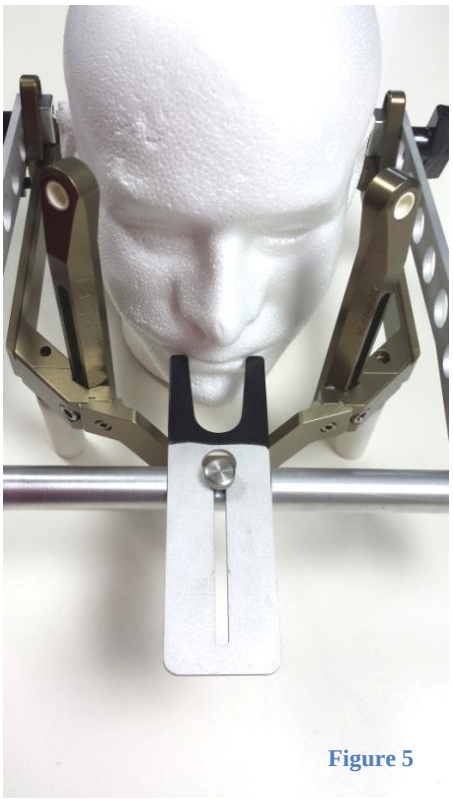

Figure 5

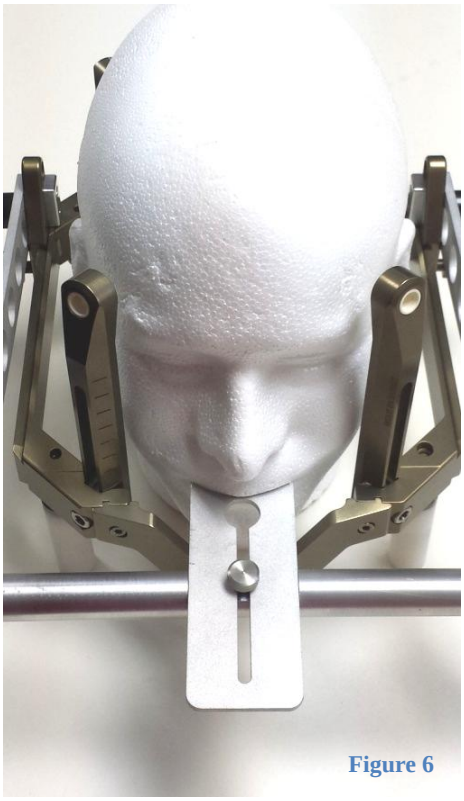

Figure 6

Setting of the Calibrated Needle Guides

The needle guides provide a mechanism for the precision injection of local anesthetic into the screw fixation sites, and indicate the correct length of screw in each position.

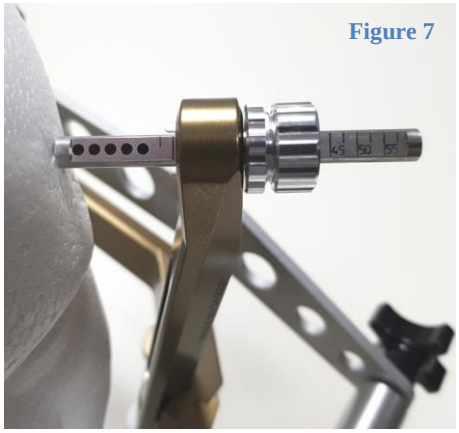

Figure 7

- With the Leksell frame held in position by the patient maintaining pressure on the bite plate, the needle guides may be pushed into place against the skull. (Figure 7). Position all four needle guides, establishing firm contact with the patient's skin.
- The scale in the needle guides provides a reference for the appropriate length of fixation screw for each site. The

reading is taken at the distal end of the bushing: the full lines immediately to the left of each number correspond to that length of fixation screw and the half lines between them designate intermediate values (Leksell screws are available in increments of 2.5 mm). In Figure 8, the guide scale indicates a fixation screw length of 40 mm at this position. Record the values at each of the sites prior to injection.

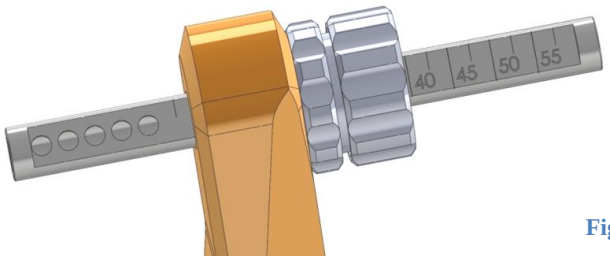

Figure 8

- Pass a needle through the needle guide and inject anesthetic subcutaneously at each of the fixation points. Typically, a large weal or "bubble" of anesthetic is deposited under the skin at the site – the needle guide is slowly retracted distally as the weal forms to leave room for the pocket of anesthetic.

Installation of Fixation Screws

With anesthetization of the screw sites accomplished, the fixation screws may be installed. For each site, select a fixation screw whose length corresponds to the reading on the needle guide previously recorded at that location.

- Fully remove the calibrated needle guides from opposing quadrants by unscrewing them from the plastic insert, and replace them with the designated length fixation screws.
- Tighten opposing screws according to the Leksell fixation frame instructions.
- Repeat this procedure for the remaining two opposing fixation sites.

Removing the Alignment Frame from the Leksell Fixation Frame

With the fixation screws installed and tightened, the alignment frame may be removed from the Leksell fixation frame.

- Loosen the thumbscrew holding the bite plate to the front bar of the alignment frame and instruct the patient to release jaw pressure on the bite plate.
- Withdraw the bite plate until the keyhole in the proximal end of the plate is aligned with the thumbscrew in the front bar, and lift it out of the frame.
- Loosen the two thumbscrews at the bottom of the dovetail clamps by three full turns.
- Grasp the front bar of the alignment frame and slide it forward in an even motion, away from the patient's head and the fixation frame. The clamps will fully disengage from the side rails of the Leksell frame, and the alignment frame may then be set aside.

Exploded View of the Tyler Alignment Frame

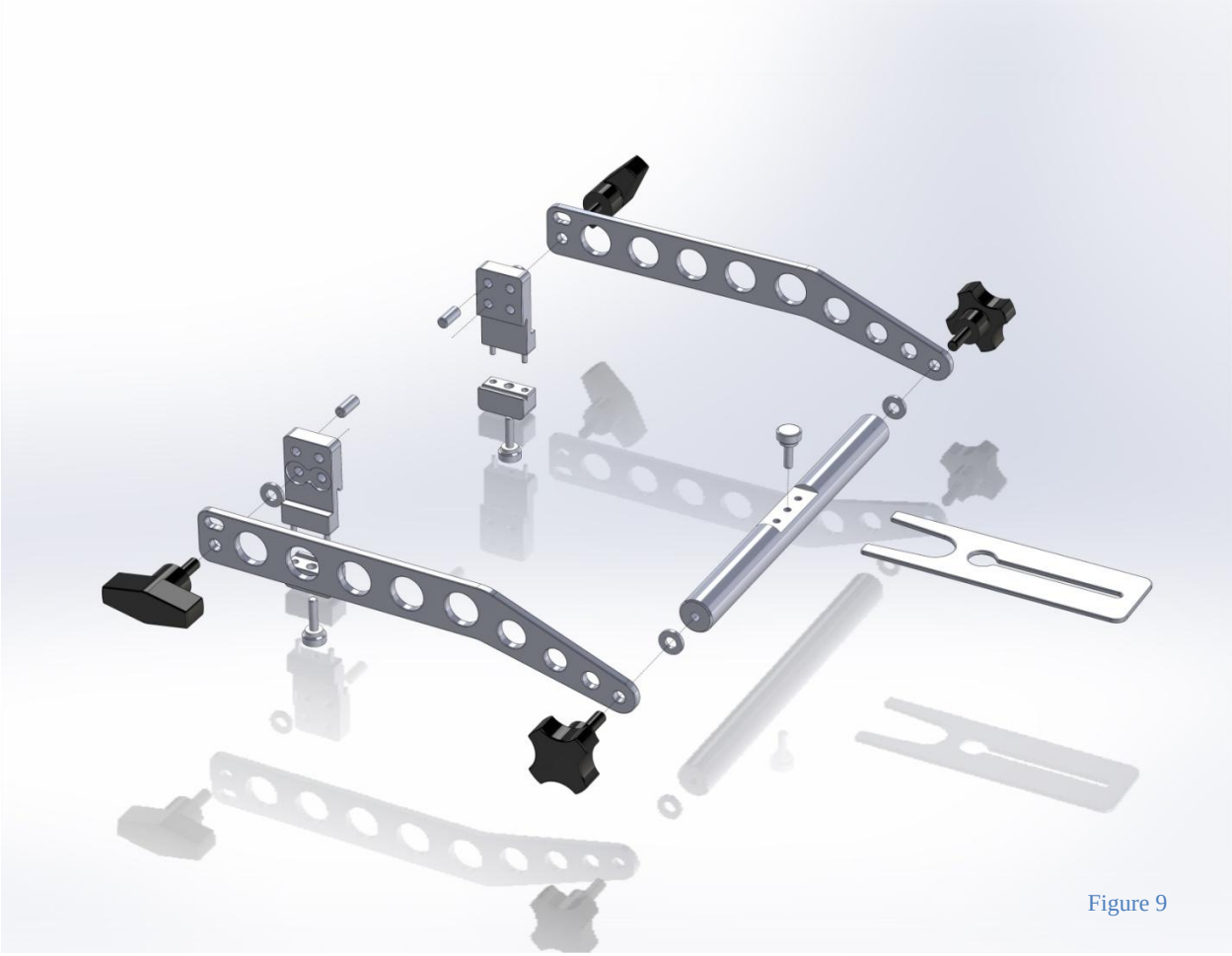

Figure 9

The diagram above may be used as a guide for assembly of the alignment frame components in the event repair or extensive cleaning is required.

Section A - Maintenance

The Tyler alignment frame requires minimal maintenance to ensure optimal operation.

- Handle all Tyler equipment with care. Any damage, however minor, can reduce treatment safety and precision. Inspect equipment prior to use. If you suspect that any component is damaged, designate the frame as ***out of service*** and contact Tyler Research immediately. Do not return a suspect frame to prep-room service without confirmation that it is fully functional.
- Periodically inspect all threads on clamping knobs and thumbscrews for signs of excessive wear and replace as necessary. Threaded components should be free-running and capable of securely clamping the relevant frame elements. Damaged threads can cause unsafe fixation of the alignment frame.

- The four locking wedge washer assemblies are critical components and must be installed precisely in the locations shown in the above exploded diagram. Note that each assembly consists of two rings whose proper orientation must be preserved – opposing wedges on the inside mating surfaces and radial serrations on the outside surfaces (see Figure 10). These assemblies are responsible for securely locking the adjustable hinges of the alignment frame and must not be altered.

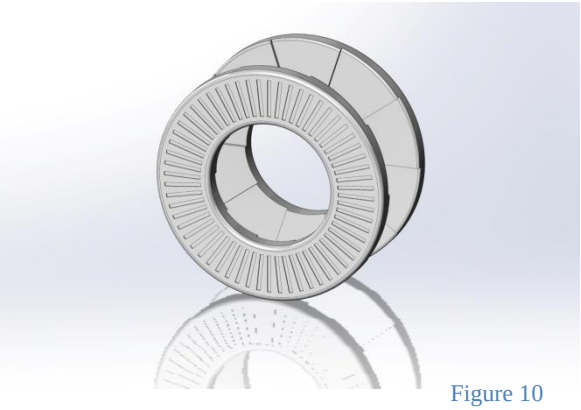

Figure 10

Section B – Contamination

In the unlikely event that the Tyler alignment frame comes into contact with blood or body tissues, it should be completely disassembled and the individual components thoroughly cleaned. Reassemble the frame according to Figure 9 Exploded View, and follow the protocols outlined in the section "Preparing the Tyler Alignment Frame" ***including the section on sterilization***.

Note that the above does not apply to contamination of the bite plate, which is a single use item, and the calibrated needle guides, which are sterilized before every procedure.

Exploded View of the Needle Guide Assembly

The collet assembly consists of a collet body and a collet collar that together apply variable compression to a captive O-ring. This, in turn, restricts mobility of the needle guide within the collet assembly. The needle guide is a smooth-bore tube with graduations corresponding to fixation screw length, and an array of holes to permit visualization of the needle at the proximal end.

Figure 11

Slip and Threaded Insertion Collet Assemblies

Two types of collet assemblies are available for the Tyler Calibration System: (1) a **threaded insertion type** which is the standard for the system (and for which the foregoing instructions are intended), and (2) a **slip insertion type** available as an accessory. As the names imply, the threaded insertion system screws into the threaded sleeve of the fixation post, while the slip insertion system slips into the threaded sleeve of the fixation post. In all other respects they are identical. Each type has its advantages:

- The Threaded Insertion System may be installed prior to placing the combined alignment and fixation frame over the patient's head. The needle guides cannot be dislodged or pushed out of the insert inadvertently and they are immediately available as soon as the frame is immobilized on the patient. Because the collets are fixed in position until unscrewed, only the calibrated needle guides can be pulled away as the weal of anesthetic forms under the skin and therefore the relative position of the needle guide in the collet is not maintained. This means that the measurements denoting fixation screw length with this system must be noted and recorded prior to injection.
- The Slip Insertion System can be installed very quickly following immobilization of the frame, and when creating a "bubble" of anesthetic at the injection site, the entire collet can be pulled away as the bubble of anesthetic forms under the skin without changing the relative position of the needle guide in the collet. The screw length indication at each site is therefore preserved as the guide assemblies are removed and may be referenced subsequently.

Figure 12 Slip Insertion System

Figure 13 Threaded Insertion System

Tyler Alignment & Calibration System with Leksell Fixation Frame