

Instruction For Use



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USA
Rx ONLY

Distributed By :



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1. User manual

1.1. Presentation

1.1.1. Destination

This kit is composed of several instruments which will be used by a trained orthopedic surgeon or neuro-surgeon to create access to the spine.

This kit is used to provide a spinal access channel through the tissue. The retractor will move apart the flesh to allow the surgeon access to the disc or at the wound bottom.



1.1.2. Intended use

The Retractor Kit is intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port, down to the bony spinal elements. These ports provide access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

DO NOT IMPLANT THE INSTRUMENTS.

1.1.3. Warnings

WARNING: Read the following handling instructions before use.

Breakage, misuse or mishandling of instruments, such as on sharp edges, may cause injury to the patient or the operative personnel.

Improper maintenance, handling or poor cleaning procedures could render the device unsuitable for its intended use or even dangerous to the patient or surgical staff and void any warranty.

1.1.4. Precautions

- Extreme care should be taken to ensure that this instrument remain in good working order.
 - o Small parts can be lost.
 - o Some instruments are sterile (probe and light mat): check that the packaging is unharmed. Check the expiry date on the sterile products.
 - o Some parts are sharp and require to be handled with care in order not to harm the patient and the medical staff.
 - o Devices must be handled with care to prevent damage. Take precautions to prevent any breakage. Instruments should not be bent or damaged in any way.
- The user of this product must be familiar and trained in use and care of the product.
- Do not use this instrument for any action for which it was not intended.
- Before the surgery, to avoid injury, always run an examination as described below. If anything is missing or doesn't seem right, call your local agent as soon as possible and discard the kit.
- Devices, that are provided non-sterile, must be cleaned and sterilized prior to use according to the directions outlined below (except otherwise stated).
- Be aware that any failure in cleaning, maintenance or usage can lead to an unusable, corroded, broken instrument that could be dangerous to the patient and the medical staff.

1.2. Convenience kit content

1.2.1. Cue card

Below are pictures of the loaded Retractor Kit. Content might be custom so the pictures below are for information only. Custom Cue Card will be included in the packaging.

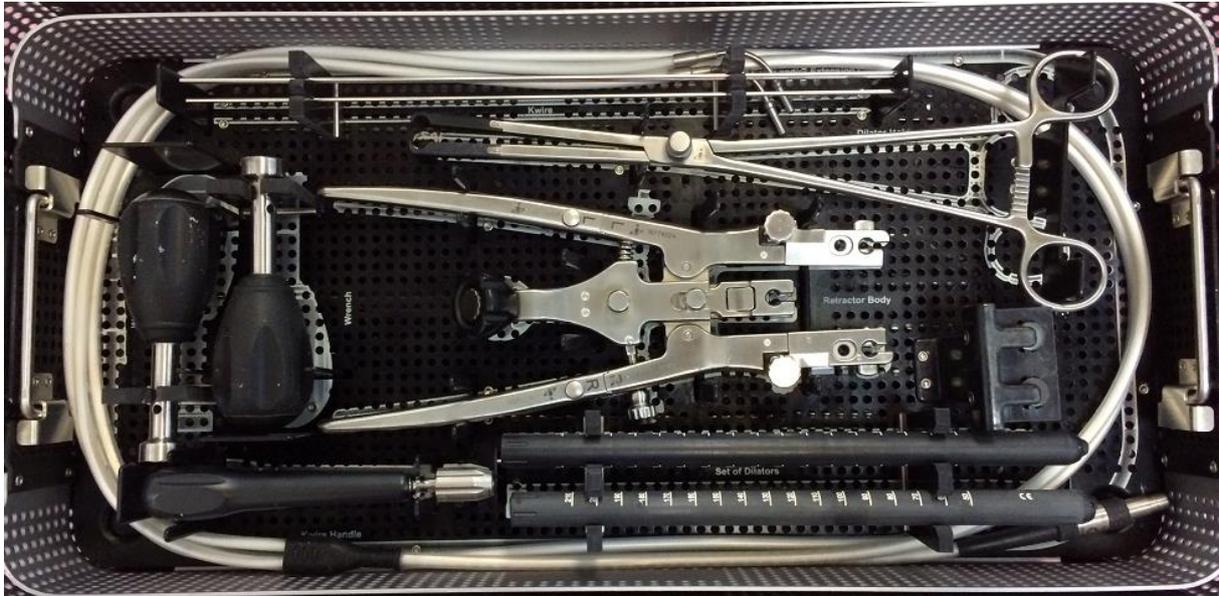


Figure 1: Case 1 - Upper level

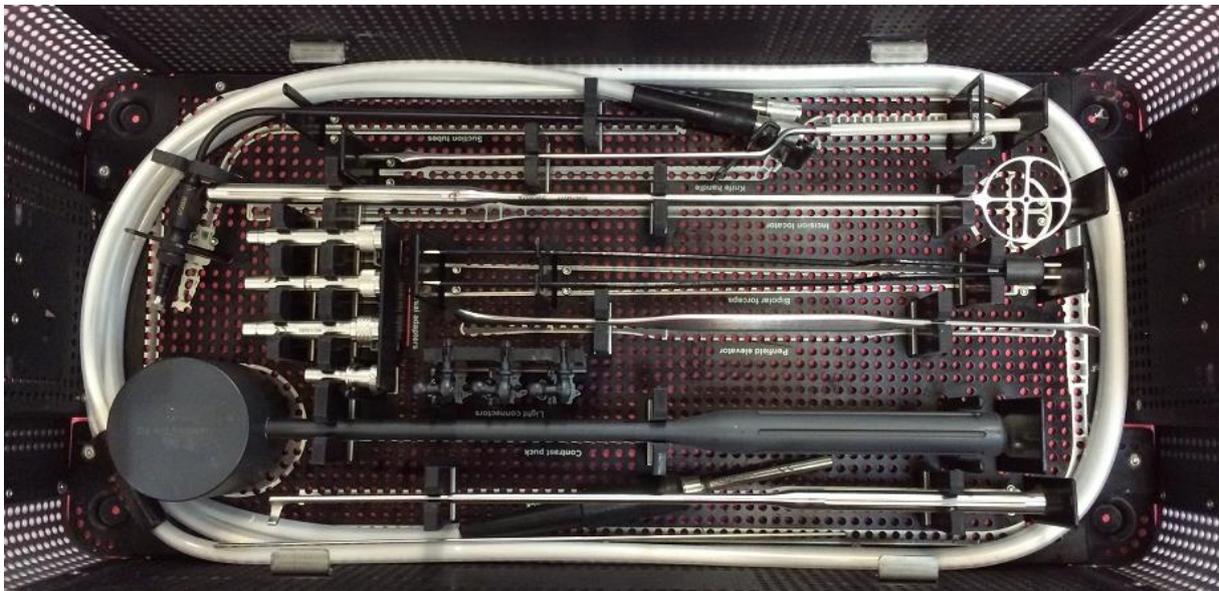


Figure 2: Case 1 - Lower level

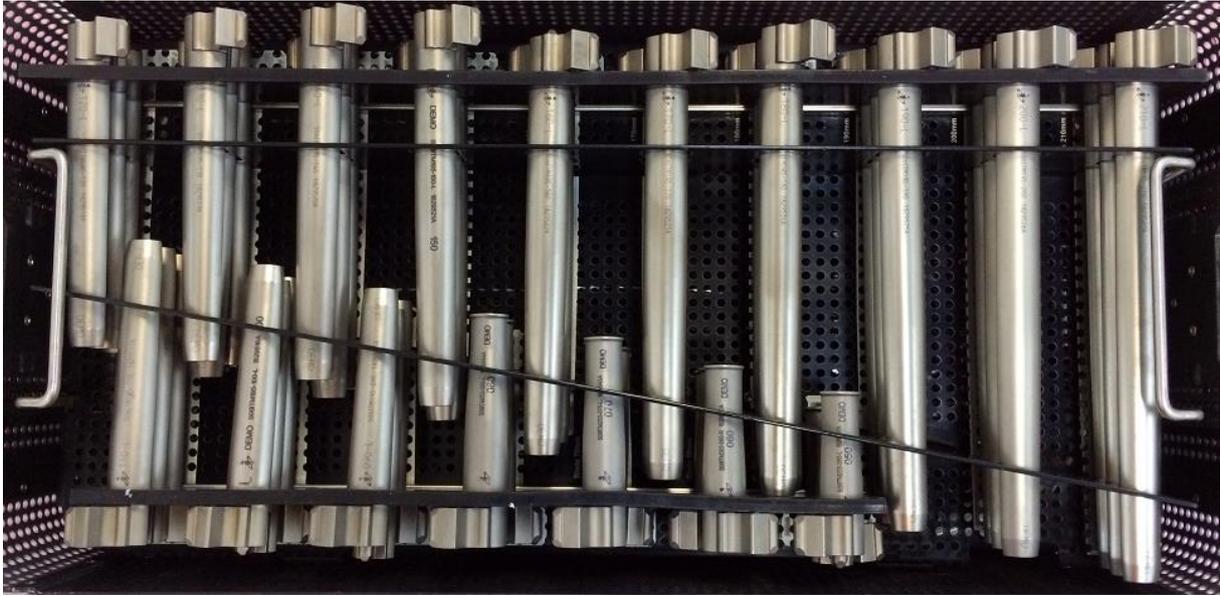


Figure 3: Case 2 – Upper level

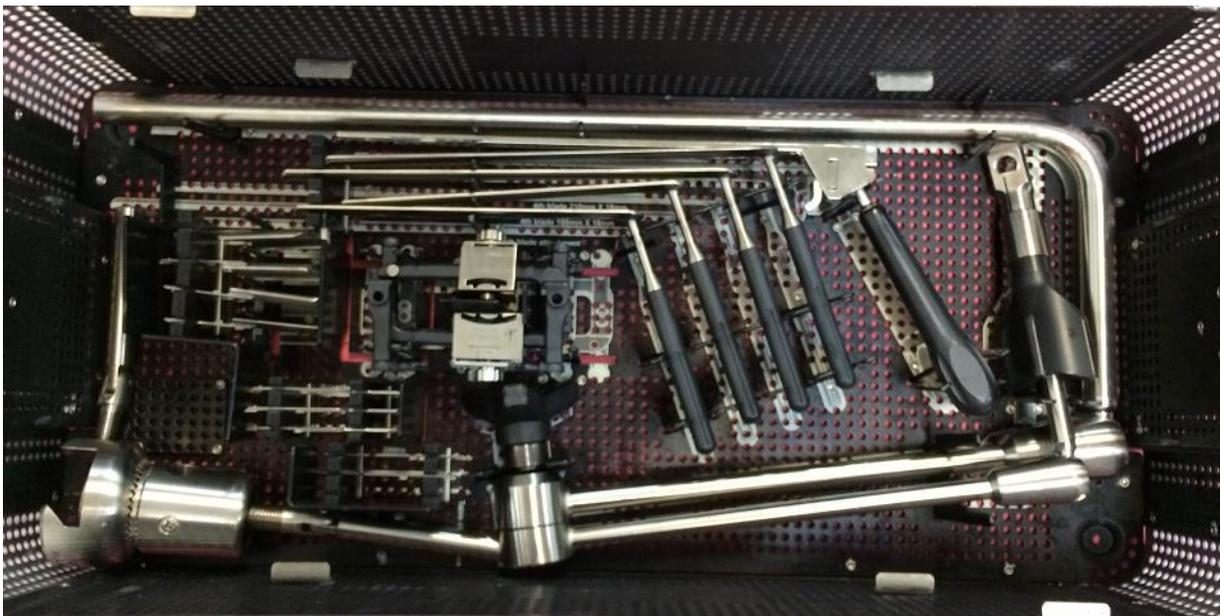


Figure 4: Case 2 – Lower level

1.2.2. *List of references and US/EU classes*

	Sterile / Non-sterile	Single-use / reusable	FDA class	510(k)	CE Class
K-wire OFIX-189	Non-sterile	Reusable	I	NA	I
Blade 100mm OFIX-195-100 Blade 110mm OFIX-195-110 Blade 120mm OFIX-195-120 Blade 130mm OFIX-195-130 Blade 140mm OFIX-195-140 Blade 150mm OFIX-195-150 Blade 160mm OFIX-195-160	Non-sterile	Reusable	I	NA	IIa
Table clamp (arm) OFIX-197	Non-sterile	Reusable	I	NA	I
Broach OFIX-200	Non-sterile	Reusable	I	NA	IIa
Shim OFIX-201	Non-sterile	Reusable	I	NA	IIa
Shim and Broach Inserter OFIX-204	Non-sterile	Reusable	I	NA	I
Wrench OFIX-208	Non-sterile	Reusable	I	NA	I
OFIX-319	Non-sterile	Reusable	I	NA	I
Disposable Probe (Sterile) S06ITM231	Sterile	Single-use only 	II	K063729	III
Disposable long light mat (Sterile) S06ITM308	Sterile	Single-use only 	I	NA	III
Dual Extension Cord for Light Mat S06ITM234	Non-sterile	Reusable	II	K901035	I
Retractor with asymmetric body OFIX-271	Non-sterile	Reusable	I	NA	I
Knife handle (Knurled) OFIX-272	Non-sterile	Reusable	I	NA	I
Contrast puck OFIX-276	Non-sterile	Reusable	I	NA	I
Incision indicator OFIX-277	Non-sterile	Reusable	I	NA	I
4th blade 12x160mm Ti OFIX-284	Non-sterile	Reusable	I	NA	IIa
4th blade attachment 12-18mm OFIX-286	Non-sterile	Reusable	I	NA	I
Rotative table clamp base S06ITM288	Non-sterile	Reusable	I	NA	I

	Sterile / Non-sterile	Single-use / reusable	FDA class	510(k)	CE Class
Dilator #1 OFIX-292-01 Dilator #2 OFIX-292-02	Non-sterile	Reusable	I	NA	I
Stacking tray OFIX-295-2	Non-sterile	Reusable	I	NA	I
Penfield OFIX-273	Non-sterile	Reusable	I	NA	I

1.2.3. Example of a sequence of actions

This documentation does not provide medical advice. The content is not intended to be a substitute for professional training regarding the medical devices or procedure depicted herein. The following sequence of actions is for informational purpose only.

Step 1: incision, dilators and nerve monitoring



Figure 5



Figure 6

Fig. 7: First spot where the incision should be by using the [incision locator](#) to locate the disc via fluoroscopy. Then make an incision with a [knife handle](#) and a blade. Insert [smallest dilator](#) in the incision. Hold steady the dilator with the [dilator holder](#) during fluoroscopy.



Figure 7

Fig. 8 & 9: If desired for a particular approach to the spine, a nerve monitoring probe can slide down the small dilator to detect nerve(s) all around the small dilator. After nerve monitoring, remove the probe and insert the [k-wire](#) onto the disc.



Figure 8

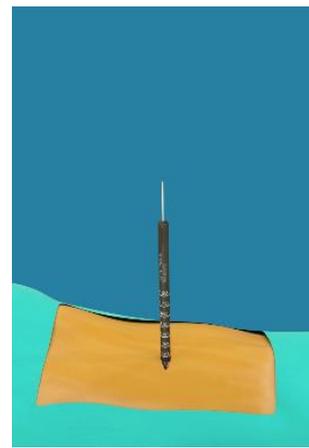


Figure 9

Fig. 10 & 11: Slide the [biggest dilator](#) onto the small one. Run nerve monitoring again if desired for surgical access. Probe can slide down the big dilator dedicated channel to allow the probe to detect nerve all around the big dilator.



Figure 10



Figure 11

Fig. 12: Remove the probe. The scale on the tube will help choosing the required blade length.



Figure 12

Step 2: distraction and fastening system

Fig 13 & 14 & 15: Take the [retractor body](#) and connect 3 [blades](#): 1 right, 1 left, 1 central. They should make a general circle with small gaps between the blades. Slide the 3 blades circle down the dilator.



Figure 13



Figure 14



Figure 15

Fig 16 & 17: Fasten the retractor body to the surgery table with the [articulated arm](#) and its table clamp. Then remove the dilators and k-wire. Single-use [light mat](#) can be used to bring light to the bottom of the wound: slide the light mat down the blade. Probe can be used again for nerve monitoring if needed.

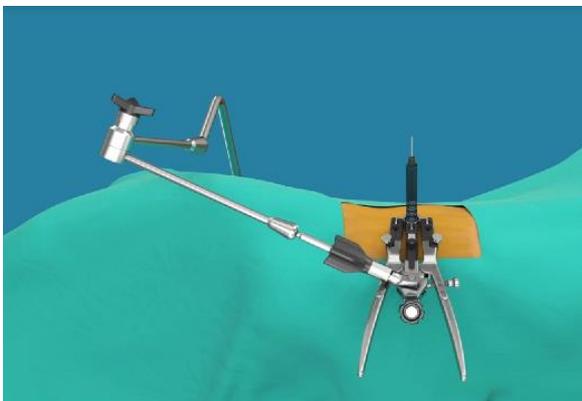


Figure 16

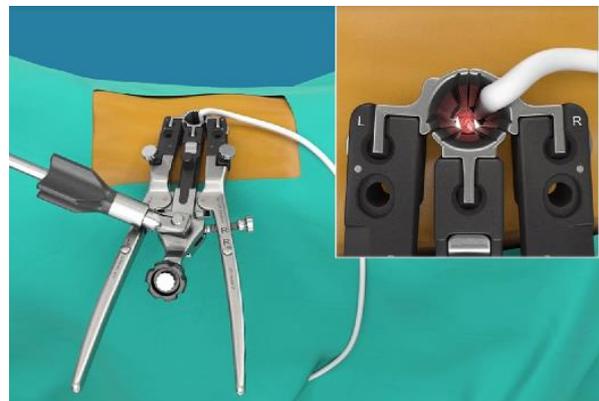


Figure 17

Fig. 18 & 19 & 20 & 21: To distract left and right blades, press both arms. Secure by screwing the lateral knob. To distract the central blade, turn the central black knob. This will allow to enlarge the access. Lateral blades can even be angled using the additional [wrench](#).

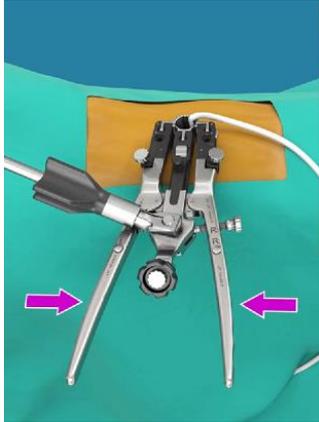


Figure 18

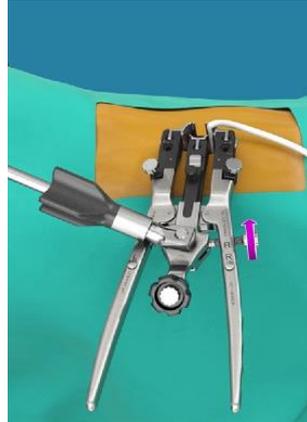


Figure 19

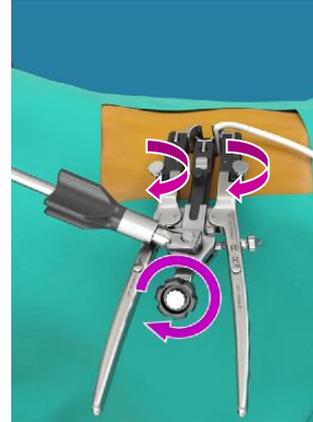


Figure 20



Figure 21

Fig. 22 & 23: Remove the arms to save some space around the access.

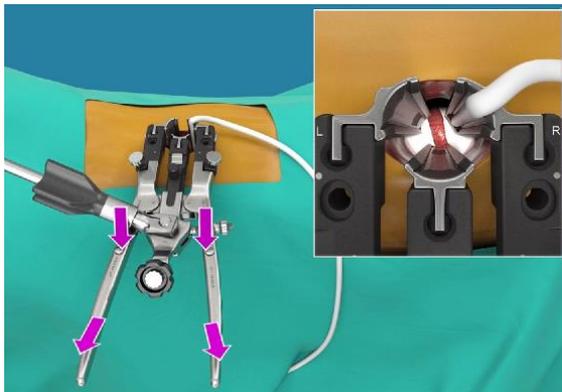


Figure 22

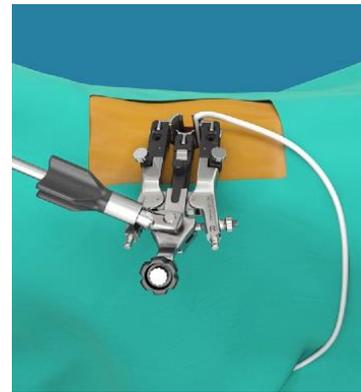


Figure 23

Fig. 24 & 25: Fasten a [broach](#) onto the [shim/broach inserter](#). Slide the broach down the blade via the dedicated groove. Insert the broach onto the disc, slight impacts on the back of the shim holder might help. Same procedure can be done to insert a [shim](#) onto the vertebral body. This will allow user to fasten the retractor body to the body.



Figure 24

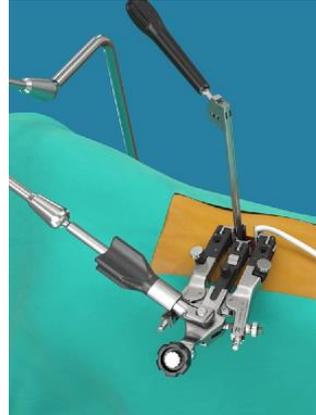


Figure 25

Step 3: Additional tools

Fig. 26 & 27 & 28: If a [4th blade](#) is required, clip a [4th blade support](#) on the top of the retractor. This support's arms can slide to mates with the retractor opening. Slide a [4th blade](#) down the support's dedicated slot. Lock its position with the additional wrench.

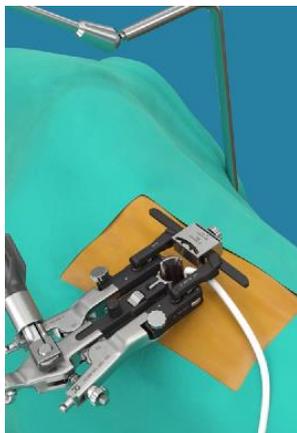


Figure 26

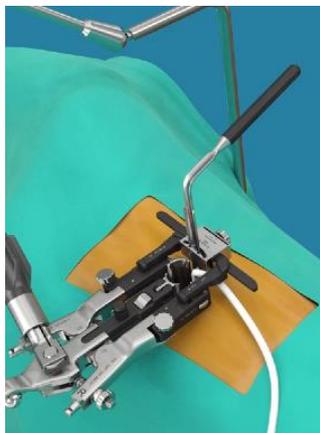


Figure 27

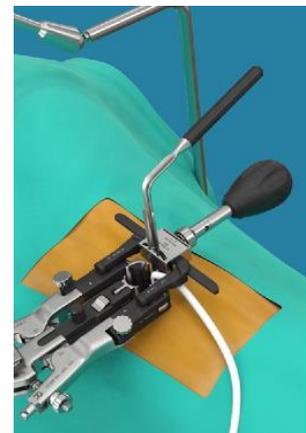


Figure 28

A [contrast puck](#) is also available. Refer to the individual product description to know more about these devices.

All the reusable devices can be stored inside the dedicated [container](#), which can also be sterilized.

1.3. Specific handling instructions

1.3.1. Incision indicator

Incision indicator is reusable. It can be used to locate the incision. Place the incision indicator cross above the incision. The device will be visible under fluoroscopy.



Figure 29

It must be handled with care to prevent damage. Take precautions to prevent tip breakage.

1.3.2. Knife handle

The Knurled Knife handle is reusable.



Figure 30

Clip the scalpel blade onto the knife handle. **Warning: scalpel blades are very sharp. They must be handled with care.**

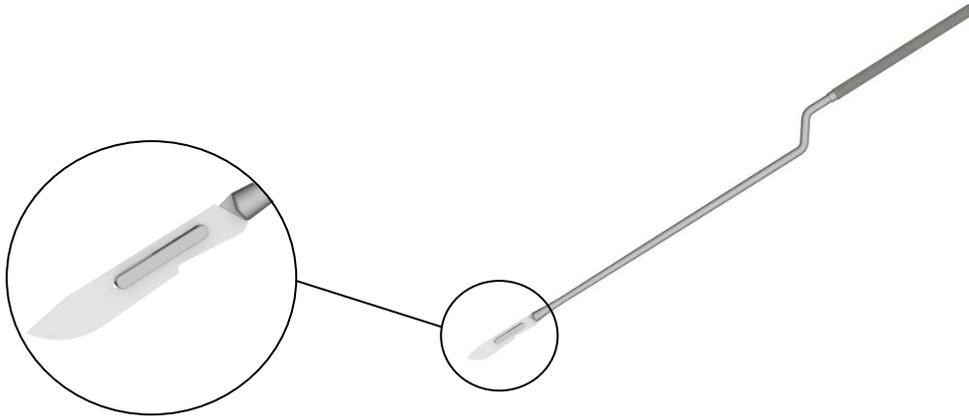


Figure 31

1.3.3. Dilators and dilator holder

Dilators and dilator holder are reusable.

Slide the smallest dilator in order to extend the incision. Slide carefully the largest dilator on top of the smallest dilator in order to extend even more the incision. Once the largest dilator is in position, it will provide the surgeon with the desired diameter where the retractor blades will fit tightly around it for the insertion of the device.

Use the dilator holder to hold the dilators (see figure 32) while performing fluoro. Dilator holder can be fastened to the table clamp to avoid surgeon hand exposure during X-rays.



Figure 32

When fully inserted, the scale on the dilator will provide an approximate depth which is a hint for the selection of the blades length.

1.3.4. *Probe*

The disposable probe is a sterile single use product. Check the expiry date and the packaging before use. Dispose after use.

WARNING: Read the own Instruction For Use of the probe before any use of the product. In'Tech can't be responsible for any misuse of the disposable probe. This Instruction for Use is included inside the packaging.



Plug the probe to a suitable electrical source via DIN 42802 touch proof connectors.

The probe can be carefully inserted in the dilator offset groove. The detection ball (located at the end of the probe) will be exposed at the end of the dilator (see next figure). **The ball probe should never stick out from the distal end of the dilator probe. Do not overstrain nor press too hard while inserting the probe.** When monitoring is done, carefully remove the probe from the dilator. Dispose the probe after use.



Figure 33

1.3.5. K-wire

The K-wire is a reusable product. **Be careful, K-wire is very sharp. Wearing gloves is recommended.**

1.3.6. Retractor body, blades and wrench

The retractor body, blades and wrench are reusable devices. The retractor body is available in an asymmetrical version where both arms can be open independently from each other. Blades are available with many lengths.

- Choose the blades size based on the information provided by the scale on the dilators (blades length depending on the thickness of the patient)

- Fix the 3 selected blades on the retractor body: they slide vertically either from the top or from beneath, until a click can be heard:

- Place a right blade (R marked) on the right arm (R marked) (see next figure)
- Place a left blade (L marked) on the left arm (L marked)
- Place a central blade (C marked) on the middle arm

- Before inserting the retractor in the wound, check that the retractor is well closed. (see figure 34. Note: Image 34 is for illustration only and may vary from the actual product. There will be a small gap between the blades when in the closed position). If necessary, screw the right and left knobs using the wrench to set back to 0 the angle of the blades (refer to figure 38 for more details). Then slide down the retractor body with its blades in the wound around the largest dilator (see figure 35).



Figure 34

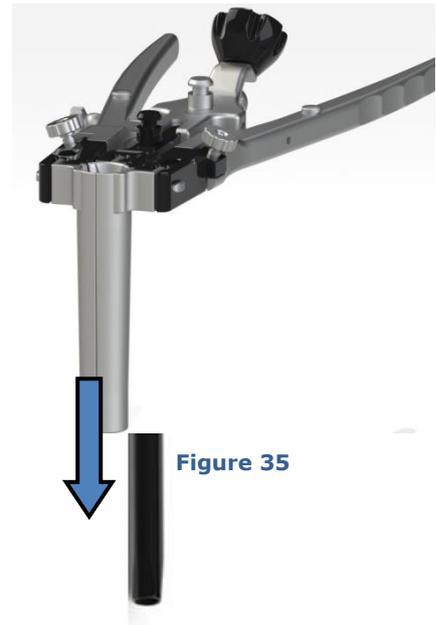


Figure 35

- Spreading is obtained via 3 different movements (see figures below):

- **a) Spreading of the lateral blades:** Squeezing the handle and screw the knob to maintain spreading as needed (see figure 37).
- **b) Tilting movement of the lateral blades:** to enlarge the space on the bottom, use the screws on the left and right arms: screwing opens angularly the blades, unscrewing closes the blades (see figure 38).
- **c) Lateral movement of the selected blades:** Screwing the big black knob will enlarge the opening, either the central blade will slide posterior or the 2 lateral blades will slide anterior, depending on where the retractor clamp is fixed to the table (see figure 39).

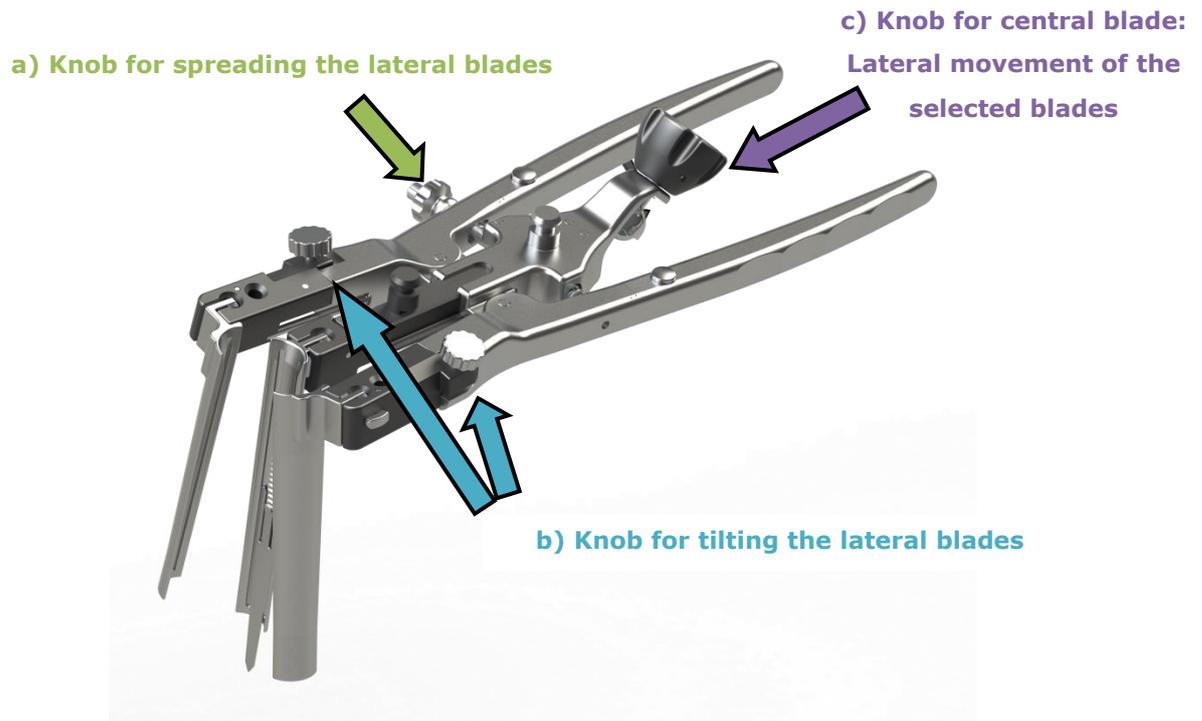


Figure 36



Figure 37



Figure 38



Figure 39

Tip 1: The wrench can be used to screw and unscrew every knob of the retractor (see example below) or of others instruments from the kit:



Figure 40

Tip 2: For more clearance around the wound, remove both arms by pressing the button and pulling the arm (see figure below).

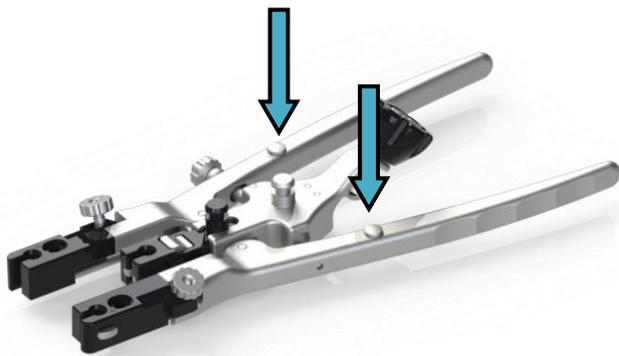
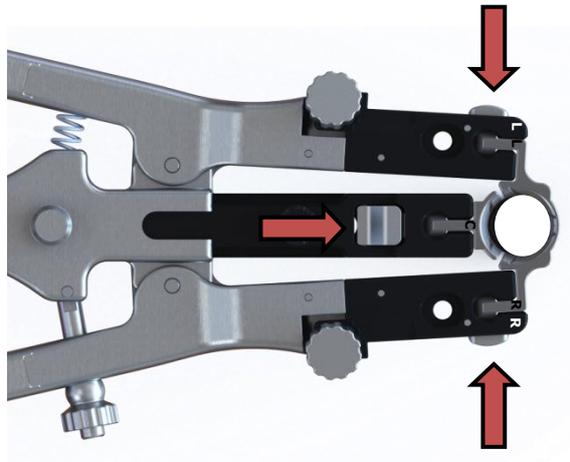


Figure 41



Figure 42

Removing advice: To remove the blades from the retractor, use the push button on each tip of the retractor and pull the corresponding blade (see figure below).



Push buttons to release the blades
Pull downwards or upwards the
corresponding blade

Figure 43

1.3.7. Table clamp and base

The table clamp is a reusable device. It's an adjustable arm which is used to fasten the retractor to the surgery table via a base, which can be either standard or rotative.

WARNING: Read the Instruction For Use of the table clamp before any use of the product. In'Tech can't be responsible for any misuse of the table clamp. This Instruction for Use is included inside the packaging.

- To fix the flexible arm to the surgery table, refer to the specific Instruction For Use of the table clamp.

Use **knob 1** to fasten the table clamp base to the surgical table rail (See figure below).

Use **knob 2** to set the height of the arm.

Use **knob 3** to lock the **three** articulations in orange.

Use **knob 4** to fasten the retractor with the arm.

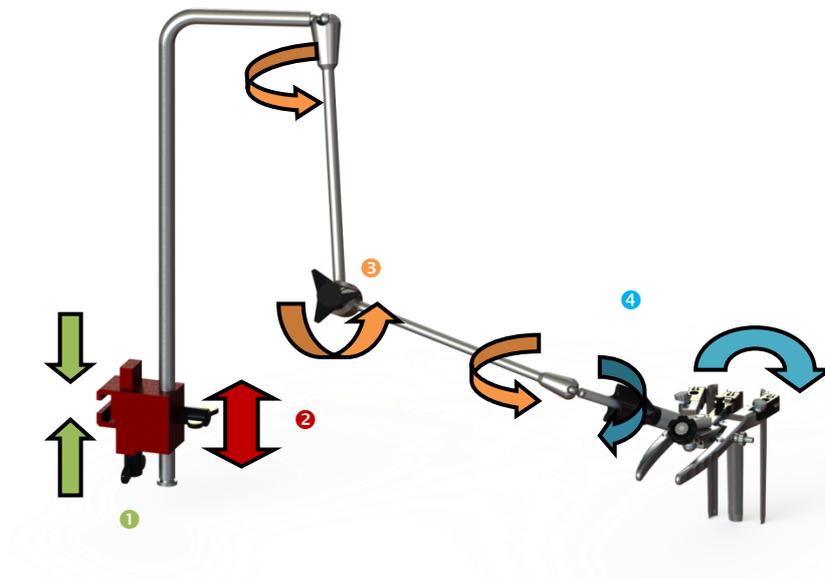


Figure 44

- Use the black connector to fix the table clamp to the retractor (see figure below). To fix the retractor on the table clamp, depending on the surgeon choice, there are 2 different options:

- **Central blade is mobile & lateral blades are fixed:** Use the **lock #1** to lock the retractor body and lateral blades. Only the central blade will slide forwards and backwards when screwing and unscrewing the black knob.
- **Central blade is fixed and lateral blades are mobile:** Use the **lock #2** to immobilize the central arm. Screwing and unscrewing the black knob will slide the lateral blades (and the retractor body) forwards or backwards.

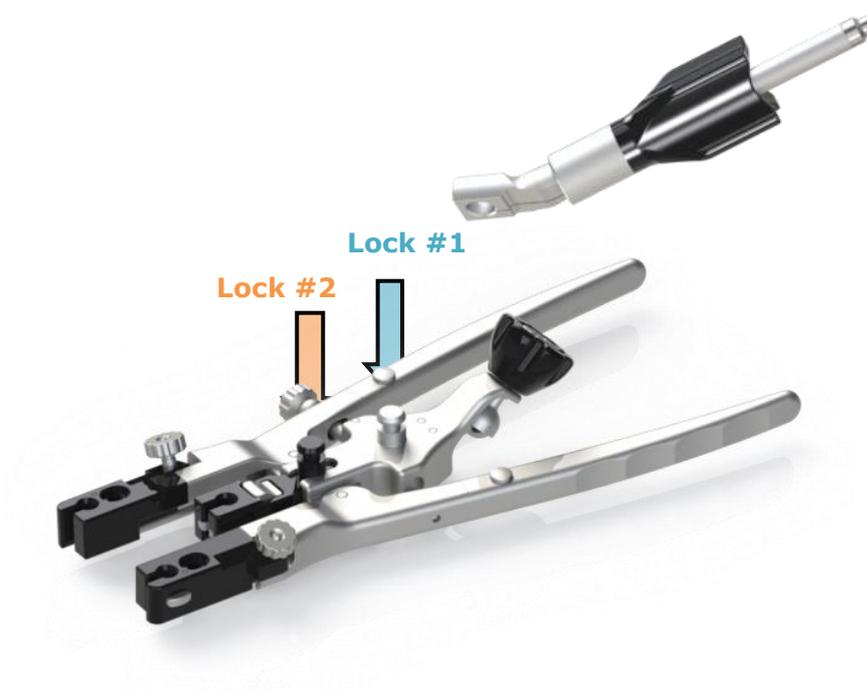


Figure 45

The table clamp can be used to fasten the dilator holder to the surgery table (refer to the previous chapter about dilator).

1.3.8. Disposable light mats and reusable extension cords

The light mats are sterile single use products. Check the expiry date and the packaging before use. Dispose after use. The extension cords are reusable.

The light mat and its optic fiber cable are employed to light up the bottom of the wound.

WARNING: Read the Instruction For Use of the light mats and the extension cords before any use of the product. In'Tech can't be responsible for any misuse of the light mats or the extension cords. Those Instructions for Use are included inside the packaging.



Connection: Use extension cord and, if needed, adaptor to plug the light mat to the light source. Below are some examples of possible configurations, depending on the type of light source.

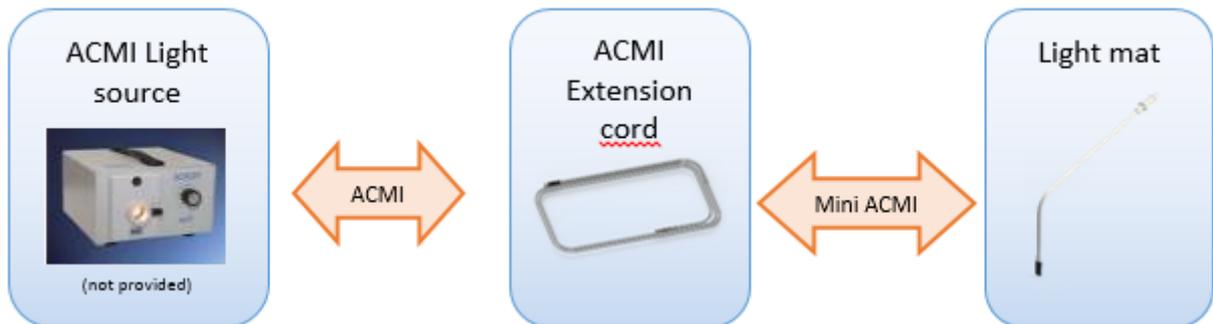


Figure 46

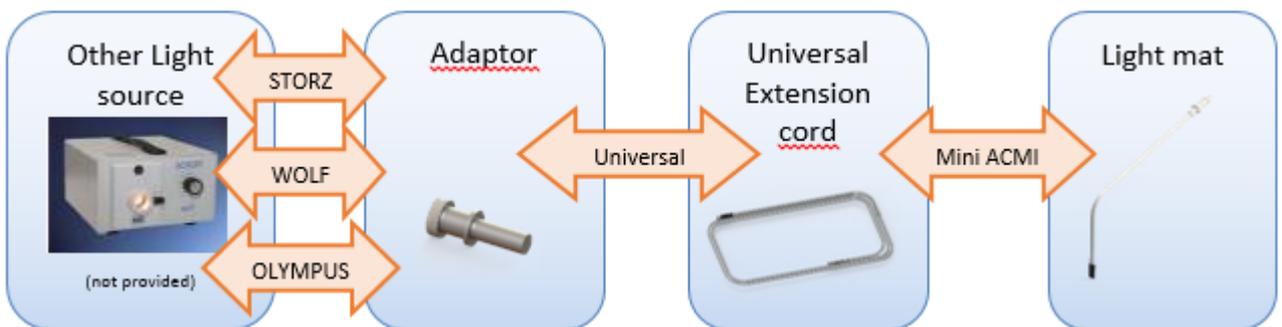


Figure 47

Insertion into blade: Slide carefully the mat through the dedicated slot inside the blade until the appropriate depth (see figure below).

Removing advice: To remove the disposable light mat, slide carefully the light mat out of the blade. Dispose after use.



Figure 48

1.3.9. Shim, broach and shim/broach holder

Shim, broach and shim/broach holder are reusable products.

- Clip together the shim (or broach) with the distal clip spring of the shim/broach holder (see picture 49). The laser marking on the shim (or broach) provides you with the correct orientation.
- Make sure the pin is fully inserted in the spring clip (see figure 50) before locking the shim (or broach) by pushing the firing pin (with the thumb) (see picture 51).



Figure 49



Figure 50



Figure 51

- Insert the shim (or broach) into the blade dedicated slot until the suitable depth (see figures 52 & 53).
- Release the shim (or broach) by pushing the trigger (with the forefinger).

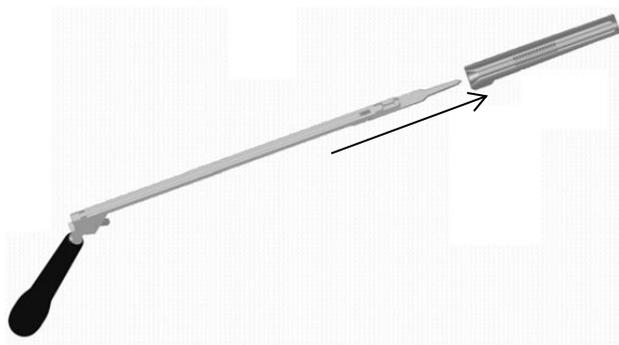


Figure 52



Figure 53

1.3.10. Optional 4th blade and its support

The 4th blade and its support are reusable.

- Clip the 4th blade support connectors to the retractor spots (see figure below) (they are the same spots used to plug the light cables in previous chapter). The arms of the 4th blade support can slide to mate with the retractor body opening.



Figure 54

- Select the suitable 4th blade (depending on the required length and width). Insert the 4th blade in the dedicated slot inside the support. At this point the 4th blade is still mobile: it can be moved **up and down** (through the groove support) or **laterally** (support is sliding), even **angularly** (see figure below).

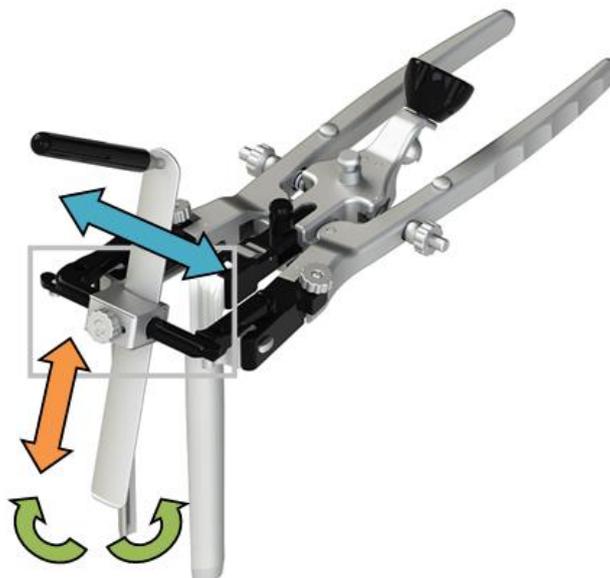


Figure 55

- Lock the height and the lateral position of the 4th blade screwing the knob with the wrench (see figure below). It will lock the opening of the arms (of the 4th blade support) too.



Figure 56

1.3.11. Penfield elevator and hockey stick

The Penfield elevator is reusable. It can be used to tuck the tissue behind the blade or reposition the tissue to allow better visibility or access.

It must be handled with care to prevent damage. Take precautions to prevent tip breakage.

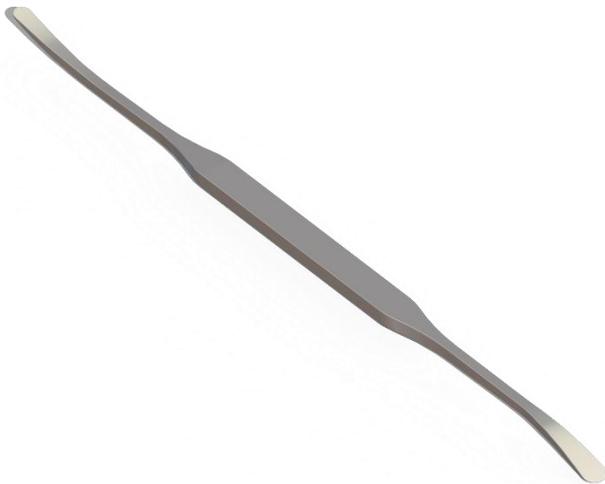


Figure 57

1.3.12. Contrast puck

Place the contrast puck above the bright area to obscure it in the fluoroscopy and make the outlines sharper. Contrast puck will only be used to obscure the picture where the surgeon decides that he needs it.



Figure 58

WARNING: Make sure that the X-Rays generator is set to the most adequate configuration for the patient and the surgeon's needs. The settings of the X-Rays generator have a massive importance on the quality, contrast and readability of the radioscopy. In'Tech can't be responsible for any misuse of the machine.

1.3.13. Stacking container

The container is reusable. It is composed of 2 sub-assembly:

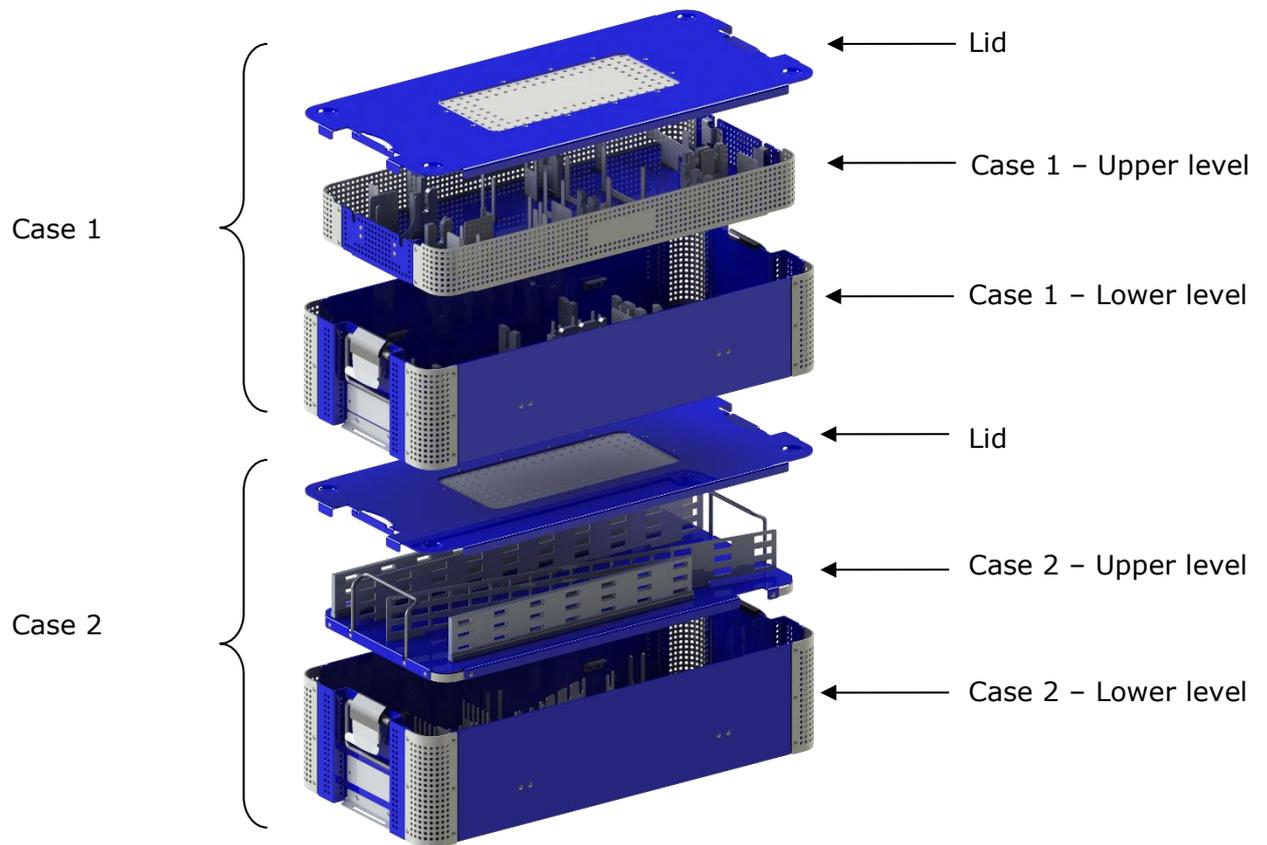


Figure 59

- Each component has its own place: use the silk-screening image on the bottom of each tray to store correctly the instruments inside the container. Or use the cue card provided.
- The container can be split into 2 sub-trays making the handling easier.

2. Instructions for cleaning, sterilization and maintenance

2.1. Examination

Instruments must always be examined by the user prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring, cleanliness of location holes or cannulations and the presence of any cracks, bending, deformation or distortion, and that all components are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise un-functional. Additional back-up instruments should be available.

Check the functionality and cleanliness of each instrument before use. If anything is missing or doesn't seem right, call your local agent as soon as possible and discard the kit.

2.1.1. Visual inspection

Make sure that:

- Laser etching and other engravings are legible.
- Discoloration, corrosion, stains or rust do not exist. If present, attempt to wipe clean in accordance with the cleaning instructions described in the dedicated paragraph.
- Insulation, coating is not damaged.
- All parts are present and free of cracks, or any other damage or deterioration.
- Cannulated instruments are free from any visible residue.

2.1.2. Functional inspection

Make sure that:

- The parts intended to move will do so freely, without sticking, binding or grinding.
- Springs are efficient.
- Retention tabs hold appropriate mating parts and are not damaged.
- The instrument will function as intended with the appropriate mating parts.
- Tips meet when appropriate.
- Threaded systems are working smoothly.

2.2. Handling prior to cleaning

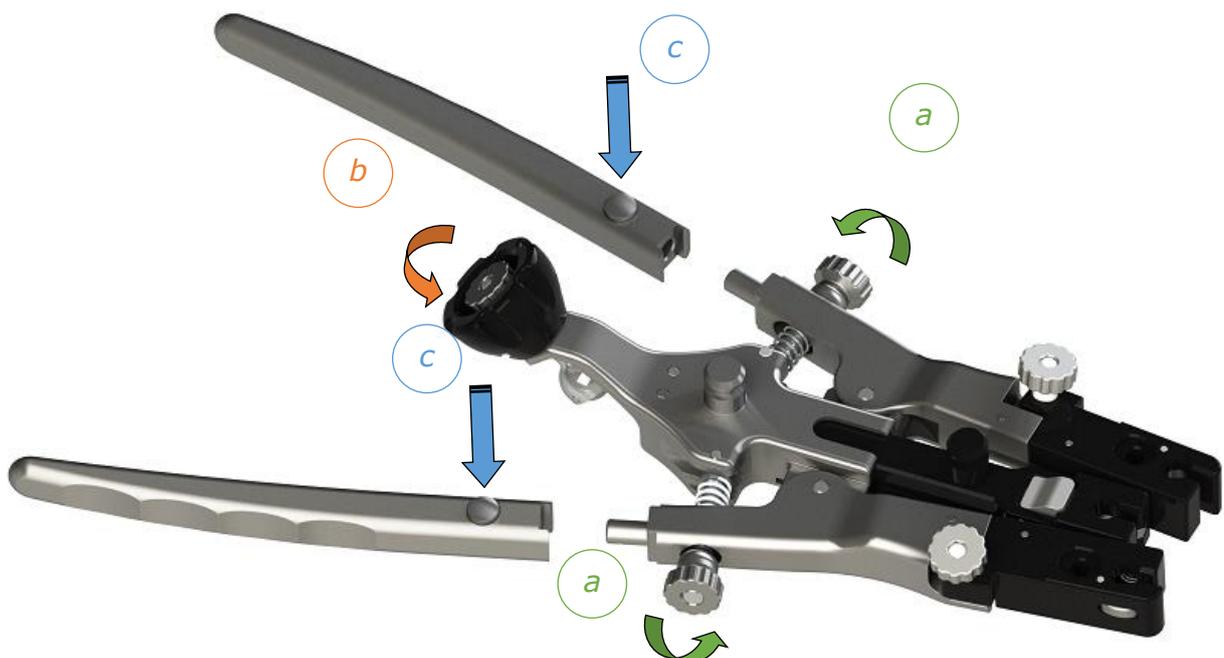
Recommendations for the handling of these surgical instruments are as follows:

- Do not let blood or tissue dry on the instrument.
- Rinse the instrument immediately after use and before decontamination.
- As much as possible, manipulate instruments made from different metals separately.
- Check the functionality and cleanliness of each instrument before use.
- Dwell time between patient use and cleaning of the devices should be minimal.
- Devices should not dry when transported from the surgery room to the cleaning room.
- Some devices should be disassembled prior to cleaning, some should be handled specifically prior to cleaning, as described below.

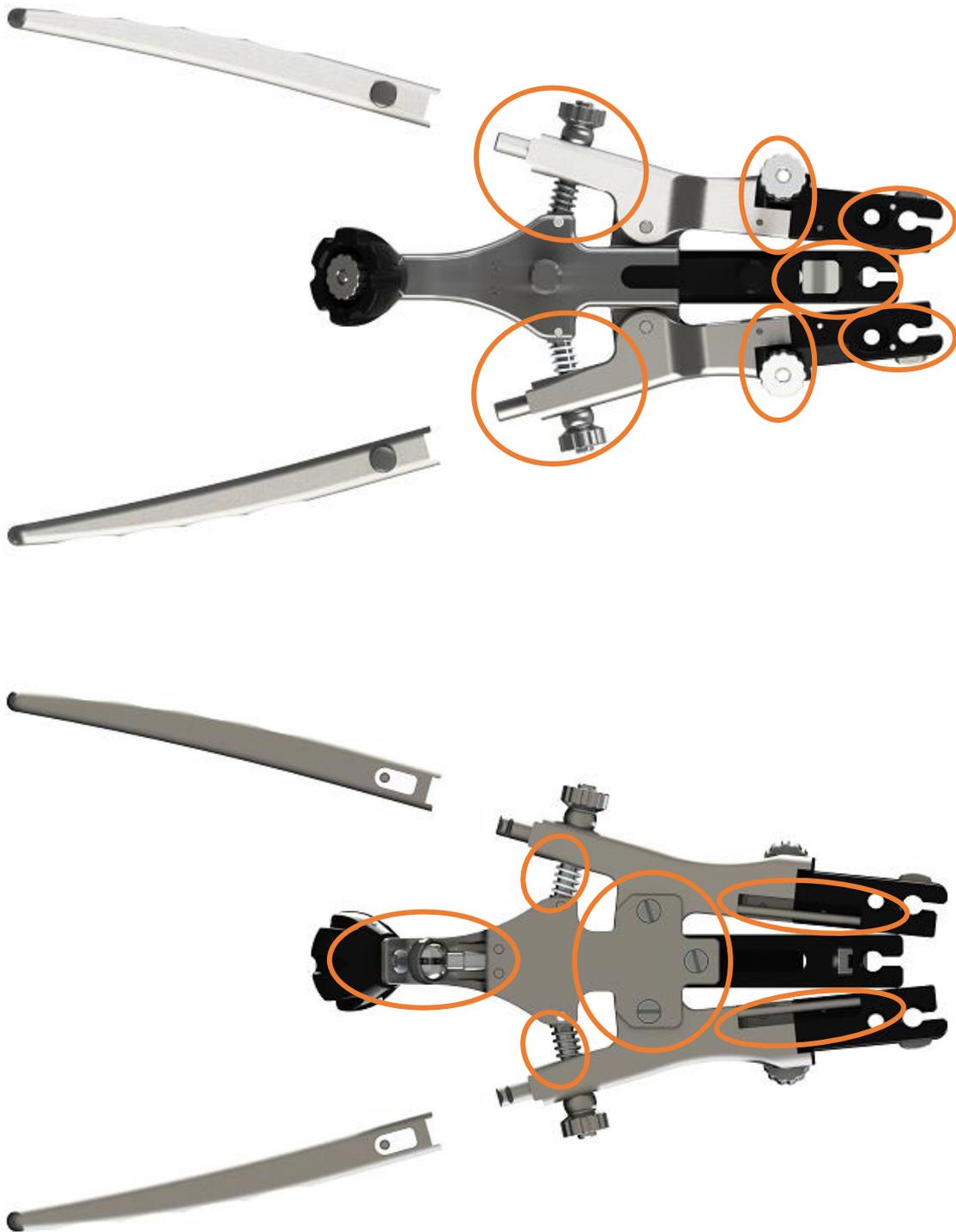
2.2.1. *Disassembling of the retractor*

Disassemble retractor by removing both arms, making sure the central arm projects to a stop having the central knob not being able to rotate any further and that the lateral knob is fully unscrewed (short rod is free to move):

- Fully unscrew the lateral nut(s) to free the short rod with the spring.
- Turn the black knob until the central arm is totally out.
- Push the left and right buttons to release both handles (see figure 27).



Areas of focus to brush and flush:



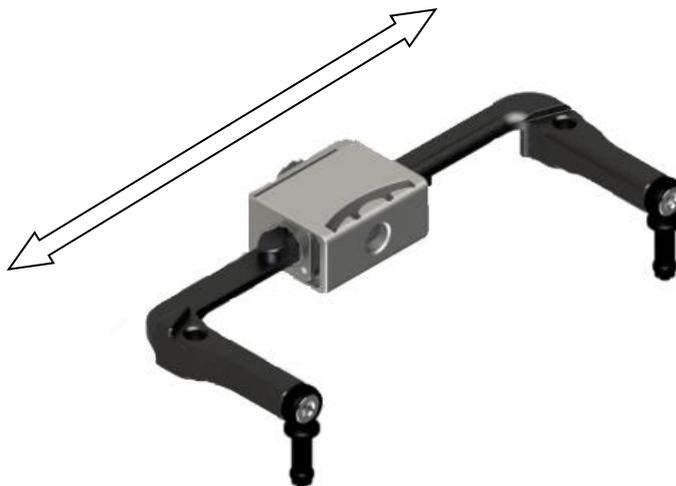
2.2.2. Shim/broach holder disassembling

Disassemble the shim/broach holder for cleaning: depress the lock (see first figure below), then lift the mechanism out of the track (see second figure below).



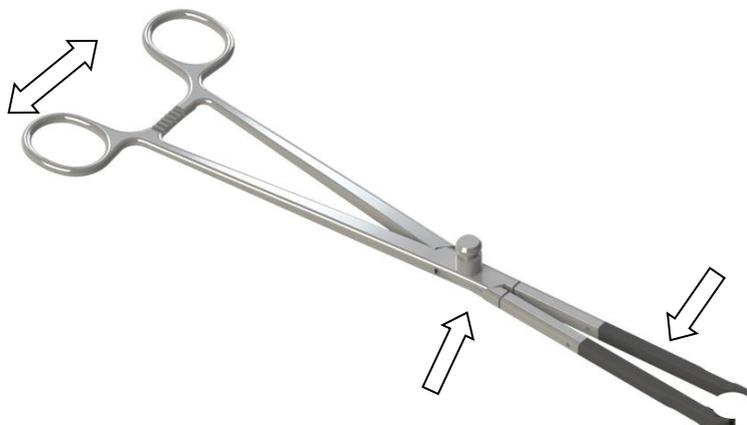
2.2.3. 4th blade support special handling care

The support must be completely opened (maximum wingspan) to maximize the access for cleaning. Screw must be totally unscrewed.



2.2.4. Dilators holder special handling care

Open the holder until the teeth on the arm is off the rack. Use a soft brush to thoroughly clean the area between the tips and the arms and the hinge (see figure below).



2.2.5. Table clamp base special handling care

The thumb screw, which fastens the tube to the base (see figure below), has to be loosened to free up the washer to allow for a more efficient cleaning and sterilization. Refer to specific IFU for more details.



2.2.6. Dilators special handling care

The tip of dilators where tantalum beads are inserted must be thoroughly brushed. Thoroughly brush the inside of both channels.



2.3. Cleaning – decontamination

Regarding the extension cords, the light cables, the table clamp and the bipolar forceps, refer to the corresponding Instruction For Use (IFU).

2.3.1. Preparation for cleaning

Disassemble any device that can be disassembled before cleaning (please see above specifications).

2.3.2. Manual pre-cleaning

- Rinse each device under ambient temperature running tap water for a minimum of 1 minute.
- Prepare a detergent bath using Enzol® at a concentration of 1 oz/gallon of lukewarm tap water in a sonication unit. Sonicate each device fully immersed in the detergent bath for a minimum of 1 minute.
- While immersed, actuate the device and brush with a soft-bristled brush and lumen brush (Spectrum M16 and 7mm x 24”) to remove all gross soil. While brushing **pay close attention to all crevices, lumens, and hard to reach areas**. Refer to specific handling care and areas of focus to brush and flush mentioned previously. Flush all crevices, lumens, and hard to clean areas with detergent while device is immersed.
- Sonicate each device for an additional 10 minutes in the detergent bath as specified above.
- Remove each device from the sonicator and rinse each device under ambient temperature running tap water for a minimum of 1 minute.
- Visually examine each device for any remaining soil.

2.3.3. Automatic cleaning

- Place each device into a washer disinfectant.
- Run the following cycle parameters set to high:

Phase	Recirculation Time (minutes)	Temperature	Detergent Type and Concentration
Pre-wash 1	02:00	Cold tap water: (14.9 - 21.8°C)	N/A

Enzyme Wash	04:00	Hot tap water: (40.1 - 48.3°C)	Enzol [®] at 1 oz/gal
Wash 1	02:00	Set point 65.5°C: (65.5 - 66.4°C)	Prolystica [®] 2X Neutral at 1/8 oz/gal
Rinse 1	00:15	Hot tap water: (47.5 - 50.2°C)	N/A
Drying	06:00	Set point 98.8°C: (69.2°C)	N/A

- Remove each device from the washer disinfectors.

DO NOT CLEAN THE SINGLE-USE PRODUCTS.

2.4. Sterilization

Please refer to chapter [2.2.5. Table clamp base special handling care](#) to free up the washer of the table clamp base before sterilization.

Regarding the extension cords, the light cables, the table clamp and the bipolar forceps, refer to the corresponding Instruction For Use (IFU).

Surgical instruments are supplied NON-STERILE. Prior to use, run following validated steam sterilization cycle:

Pre-Vacuum steam sterilization Full cycle:	Gravity steam sterilization Full cycle:
Sterilization temperature - 132°C (270°F) Sterilization exposure time - 4 minutes	Sterilization temperature - 135°C (275°F) Sterilization exposure time - 10 minutes
Dry time - 30 minutes	Dry time - 30 minutes

DO NOT STERILIZE THE SINGLE-USE PRODUCTS.

2.5. Storage

The devices have to be stored in dry conditions: area shall be ventilated, safe from dust, humidity, insects and others pests, any other potentials contamination sources. No extreme temperature and humidity rate are allowed.

The user have to prevent any mix up, damage, deterioration, contamination, or another adverse effects to the products during the handling and the storage.

Regarding the probe, the light mats, the extension cords, the light cables and the table clamp, refer to the corresponding Instruction For Use (IFU).

Be aware that the storage dwell time of sterile products is limited by the sterilization expiry date.

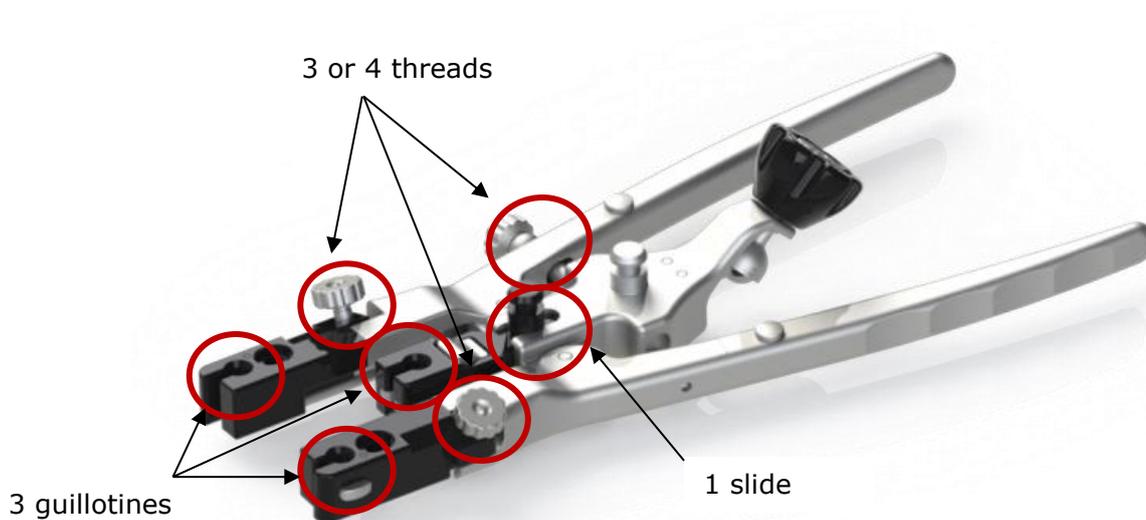
2.6. Maintenance

- Use surgery lubricant before each use. Apply only where it is recommended in the following pictures (red circles).

- If instruments were disassembled prior to cleaning and sterilization, reassemble.

WARNING: DO NOT lubricate any part which will be in contact with the patient.

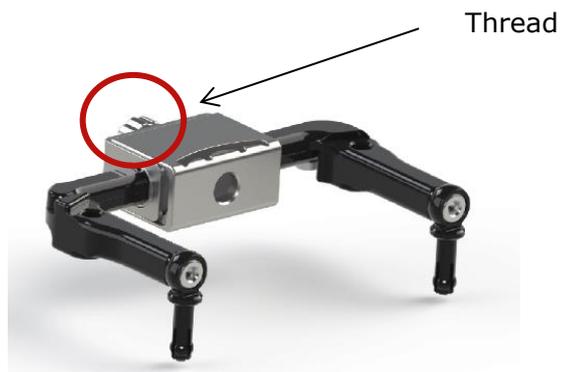
2.6.1. Retractor



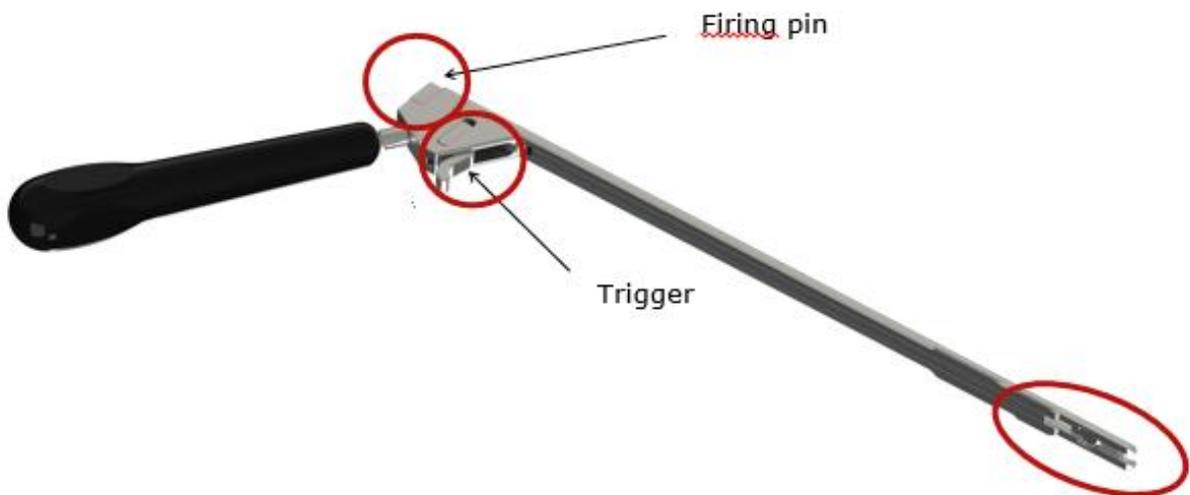
2.6.2. Table clamp connector



2.6.3. 4th blade support



2.6.4. Shim holder



2.7. Complaints

Any Health Care Professional who has any complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, effectiveness and/or performance of surgical instruments should notify Orthofix.

Orthofix must be notified immediately by telephone, fax or written correspondence of any serious accident or if there has been a risk of a serious accident which may or has caused the death or serious deterioration in health of a patient or user. When filling a complaint, please provide the name(s), serial numbers(s), number(s) of the lot of the component(s) in question, the name and address of the person making the complaint, the nature of the complaint with as many details as possible and notification of whether an answer is requested.

For the following devices:

- Light cables and adaptors
- Surgery table arm and base
- Bipolar forceps
- Single-use products

2.8. Contact

Orthofix

3451 Plano Parkway

Lewisville, Texas 75056 U.S.A

☎ : 1-888-298-5700

www.orthofix.com

3. Chart of medical device symbols used

	Manufacturer
	Date of manufacture (YYYYMM or YYYY)
	Caution, consult accompanying documents
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Keep product dry
	Batch code / lot number
	Consult Instructions for Use
	CE mark
	Non sterile

	Sterile EO
	Catalog, reorder or reference number
	Do not use if package is damaged
	Single use only
	Expiry date
	Latex free