GEN III RETRACTOR SYSTEM

Next Generation Retractor for Posterior and Lateral Approach

Distributed by: SeaSpine
Summary

1. User manual .................................................................................................................. 4

1.1. Presentation ................................................................................................................. 4

1.1.1. Destination .............................................................................................................. 4

1.1.2. Intended use .............................................................................................................. 4

1.1.3. Warnings .................................................................................................................. 5

1.1.4. Precautions .............................................................................................................. 5

1.2. Kit content .................................................................................................................. 6

1.2.1. Cue card ................................................................................................................... 6

1.2.2. List of references and US/EU classes ....................................................................... 8

1.3. Specific handling instructions .................................................................................... 10

1.3.1. Incision locator ....................................................................................................... 10

1.3.2. Knife handle ........................................................................................................... 10

1.3.3. Dilators and dilator holder ....................................................................................... 11

1.3.4. Probe ....................................................................................................................... 12

1.3.5. K-wire, K-wire handle and K-wire cap .................................................................... 13

1.3.6. Retractor body, blades and wrench ......................................................................... 13

1.3.7. Table clamp and base ............................................................................................. 19

1.3.8. Disposable light mats and accessories .................................................................... 21

1.3.9. Reusable light cables and accessories .................................................................... 23

1.3.10. Shim, broach and shim/broach holder .................................................................. 24

1.3.11. Threaded shim and 2.5mm hex screwdriver ......................................................... 25

1.3.12. Optional blade extension ....................................................................................... 26

1.3.13. Optional 4th blade and its support ....................................................................... 27

1.3.14. Penfield elevator and hockey stick ....................................................................... 28

1.3.15. Bipolar forceps ...................................................................................................... 29

1.3.16. Suction tube ......................................................................................................... 30

1.3.17. Contrast puck ....................................................................................................... 31

1.3.18. Stacking tray ........................................................................................................ 32
2. Instructions for cleaning, sterilization and maintenance…………………………33

2.1. Examination ..................................................................................................33

2.1.1. Visual inspection..........................................................................................33

2.1.2. Functional inspection..................................................................................33

2.2. Handling prior to cleaning............................................................................34

2.2.1. Disassembly of the retractor body...............................................................34

2.2.2. Shim/broach holder disassembling............................................................36

2.2.3. 4th blade attachment special handling recommendation..........................36

2.2.4. Dilator holder special handling recommendation.....................................37

2.2.5. Table clamp base special handling recommendation..............................37

2.2.6. Dilators special handling recommendation..............................................37

2.2.7. Suction tube special handling recommendation........................................38

2.3. Cleaning – decontamination......................................................................39

2.3.1. Preparation for cleaning..............................................................................39

2.3.2. Manual pre-cleaning..................................................................................39

2.3.3. Automated cleaning...................................................................................40

2.4. Sterilization..................................................................................................41

2.5. Storage.........................................................................................................41

2.6. Maintenance ................................................................................................42

2.6.1. Retractor...................................................................................................42

2.6.2. Table clamp connector..............................................................................42

2.6.3. 4th blade attachment.................................................................................43

2.6.4. Shim holder...............................................................................................43

2.7. Complaints...................................................................................................44

2.8. Contact..........................................................................................................44

3. Chart of medical device symbols used............................................................45
1. User manual

1.1. Presentation

1.1.1. Destination

This kit is comprised of several instruments which will be used by a trained orthopedic surgeon or neuro-surgeon to create a lateral or posterior access to the spine. This kit is used to provide a spinal access channel through the tissue. The retractor will spread flesh & tissues apart to provide surgeon with access to the spine (disc or vertebrae), or at the bottom of the chosen surgical site.

![Retractor Kit Components](image)

Figure 1

1.1.2. Intended use

The Retractor Kit is intended to provide the surgeon with minimally invasive surgical access to the spine by allowing controlled positioning of the access portal, for posterior or lateral approach of the spine. These portals 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 remains in good working condition.**
  - Small parts can be lost.
  - Some instruments are sterile (probe and light mat): check that the packaging is unharmed. Check the expiration date on the sterile products.
  - Some parts are sharp and require handling with care in order not to harm the patient or the medical staff.
  - 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.
- Wearing gloves is mandatory to handle the device.
1.2. Kit content

1.2.1. Cue card

Below are pictures of the fully loaded Retractor Kit. Content might be customized so the pictures below are for information only.

Figure 2: Case 1 - Upper level

Figure 3: Case 1 – Lower level
Figure 4: Case 2 – Upper level

Figure 5: Case 2 – Lower level
### 1.2.2. List of references and US/EU classes

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Sterile / Non-sterile</th>
<th>Single-use / Reusable</th>
<th>FDA class</th>
<th>510(k)</th>
<th>CE Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>K-wire S06ITM189/365</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Blade S06ITM195/203/355/356/366</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>Broach S06ITM200</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>Shim S06ITM201/353</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>Shim holder S06ITM204</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>K-wire handle S06ITM206</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>K-wire cap S06ITM207</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
</tbody>
</table>

**Single-use pedicle probe S06ITM231**
- **Single-use only**
- Sterile
- II K063729
- III

**Single-use light cables S06ITM232/308**
- **Single-use only**
- Sterile
- I NA III

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Sterile / Non-sterile</th>
<th>Single-use / Reusable</th>
<th>FDA class</th>
<th>510(k)</th>
<th>CE Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blade larger extension S06ITM233</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>Reusable light cables S06ITM234/235/236</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K901035</td>
<td>I</td>
</tr>
<tr>
<td>Knife handle S06ITM272</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Double spatula S06ITM273</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Bipolar forceps S06ITM274</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K123478</td>
<td>NA</td>
</tr>
<tr>
<td>Contrast puck S06ITM276</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Incision locator S06ITM277</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Suction tube S06ITM279/364</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>One side extension S06ITM280 &amp; S06ITM281</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>4th blade 6, 12, 18mm S06ITM284/285/350</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>4th blade attachment S06ITM286/339/349/368</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Rotative base S06ITM288</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Dilator S06ITM292</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Component</td>
<td>Sterile / Non-sterile</td>
<td>Single-use / reusable</td>
<td>FDA class</td>
<td>510(k)</td>
<td>CE Class</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------</td>
<td>-----------------------</td>
<td>-----------</td>
<td>--------</td>
<td>----------</td>
</tr>
<tr>
<td>Universal adaptor S06ITM268/269/270/278</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K901035</td>
<td>I</td>
</tr>
<tr>
<td>Short universal adaptor cable S06ITM289</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K901035</td>
<td>I</td>
</tr>
<tr>
<td>Light cable with UNIV end S06ITM293</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K901035</td>
<td>I</td>
</tr>
<tr>
<td>Extension cord with UNIV end S06ITM294</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>II</td>
<td>K901035</td>
<td>I</td>
</tr>
<tr>
<td>Hockey stick S06ITM297</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Base for table clamp S06ITM303</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Threaded shim S06ITM305</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>IIa</td>
</tr>
<tr>
<td>2.5mm hex screwdriver S06ITM309</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Dilator holder S06ITM319</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Retractor with symmetric body S06ITM337</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Wrench S06ITM340</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Retractor with asymmetric body S06ITM343</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Tray S06ITM351</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
<tr>
<td>Table clamp S06ITM358</td>
<td>Non-sterile</td>
<td>Reusable</td>
<td>I</td>
<td>NA</td>
<td>I</td>
</tr>
</tbody>
</table>

**WARNING:** Retractor should be used only with devices provided in the kit. No technical modification should be done to the retractor or any accessory without the formal agreement of the Manufacturer.
1.3. Specific handling instructions

1.3.1. Incision locator

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

![Figure 6](image)

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

1.3.2. Knife handle

 Knife handle is reusable.

![Figure 7](image)

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

Dilators and dilator holder are reusable.

Carefully engage the smallest dilator in the incision to initiate dilation process. Carefully slide the largest dilator on top of the smallest dilator in order to further dilate the access channel. Once the largest dilator is in place, it will provide the surgeon with the desired diameter so the retractor blades will fit tightly around it for the insertion of the device.

Use the dilator holder to hold the dilators (see next figure) during X-rays.

When fully inserted, markings on the dilators will provide approximate depth of the spine which will guide surgeon in selection of appropriate blade 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 probe’s own Instruction For Use before any use of the product. InTech Medical can't be responsible for any misuse of the disposable probe. This Instruction for Use is included inside the packaging.

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

The probe can be carefully inserted in the dilator’s offset channel. The probe’s tip should shoulder on dilator-end, leaving the spherical monitoring tip (located at distal-end of the probe) exposed (see next figure). **The tip of the probe should never stick out from the distal end of the dilator probe. Do not overstrain nor press too hard while inserting the probe.** Once monitoring is completed, carefully remove the probe from the dilator. Dispose of probe after use.

![Figure 10](image-url)
1.3.5. K-wire, K-wire handle and K-wire cap

The K-wire and the K-wire handle are reusable products. **Be careful, K-wire is very sharp. Special care is recommended.**

Using the K-wire handle or K-wire cap is recommended for insertion of the K-wire. Insert the K-wire into the handle: (see figure 11 & figure 12). **Beware of orientation upon insertion: sharp-end of K-wire should be on opposite side of the K-wire handle.** Screw and unscrew the chuck to secure and release the K-wire. K-wire can slide down the dilator’s dedicated channel (centered cannula of smallest dilator) and be inserted into disc-space.

![Figure 11](image1)

![Figure 12](image2)

1.3.6. Retractor body, blades and wrench

The retractor body, blades and wrench are reusable devices. The retractor body is available in 2 versions: symmetrical, where both arms open symmetrically; or asymmetrical, where both arms can be open independently from each other. Blades are available in various lengths.

- Choose the blade size according to the markings on dilators’ outer diameter (blade length to be adjusted depending on the patient’s size, selected surgical site for the surgery, or on the surgeon's needs).
- Attach the 3 selected blades to the retractor body: you may engage them by either top-loading or bottom-loading them into arms until a click can be heard:

- Place a right blade (marked “R”) on the right arm (marked “R”)
- Place a left blade (marked “L”) on the left arm (marked “L”)
- Place a central blade (marked “C”) on the middle arm (marked “C”)

NB: knobs on either side of right & left arms to firmly lock the blades.

- Before inserting the retractor into the surgical site, check that the retractor is well closed: blades shall form a closed circle (see figure 13). If necessary, screw the right and left nuts using the wrench to set back the blades to initial 0° angle (refer to figure 15 for more details). Then, slide the retractor body with the blades down into the surgical site around the largest dilator (see figure 14).
- Opening of Retractor body can be achieved via 4 different movements (see figures below):

- **a) Opening of the Right & Left retractor arms**: Squeeze the handle and screw the knob to spread open retractor as needed (see figure 17).

- **b) Towing of the Right & Left blades**: to expand the space bottom of surgical site, individually screw/unscrew the torx nuts on the left and right arm to adjust towing of blades: screwing the nuts will tilt the blades outwards 12.5°, unscrewing them closes the blades (see figure 18).

- **c) Retraction of the central blade**: Depending on what reference is chosen for the table clamp to lock onto retractor body (docking central blade or docking R & L blades), turning the large proximal knob clockwise will result in opening of retractor blades, either by retracting the central blade or displacing Right & Left blades forward (see figure 19).

- **d) Towing of the central blade**: screw the nut to angle the central blade (see figure 20)
Figure 17

Closed retractor

Figure 18

Spreading the lateral blades

Figure 19

Tilting of both lateral blades

Figure 20

Retraction of the central blade

Figure 21

Towing of the central blade
Tip 1: The wrench can be used to screw and unscrew every knob & nut on the retractor (see example below).

![Figure 22](image)

Tip 2: To reduce overall cumbersomeness of retractor once in satisfactory position, surgeon may remove both arms by pressing the quick-release button and pulling the arm backwards to disengage from body (see figures below).

![Figure 23](image)

![Figure 24](image)
Removing advice: To remove the blades from the retractor:

- First unscrew the lateral knobs:

![Unscrew both knobs to release the R&L push buttons](image1)

Figure 25

- Then use the push button on each tip of the retractor and remove the corresponding blade (see figure below).

![Push buttons to release the blades. Pull downwards or upwards to disengage the blade](image2)

Figure 26
1.3.7. *Table clamp and base*

The table clamp is a reusable device. It's an adjustable arm that is used to fasten the retractor to the surgery table via a rotative base.

*WARNING: Read the Instruction For Use of the table clamp before manipulation of the product. In’Tech Medical won’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 Instructions For Use for 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 and angulation of the arm.

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

Use **knob 4** to lock retractor to the arm.

*Figure 27*
- Use the black connector to fix the table clamp to the retractor (see figure below). To fix the retractor onto the table clamp, depending on the surgeon’s choice, there are 2 different options:

- **Central blade is mobile & Right & Left blades are fixed:** Dock table arm to the **docking peg #1** to secure the retractor body and R&L blades. Only the central blade will slide forwards and backwards when screwing and unscrewing the large proximal knob.

- **Central blade is fixed and Right & Left blades are mobile:** Dock table arm to the **docking peg #2** to immobilize the central arm. Screwing and unscrewing the black knob will slide the Right & Left blades (and the retractor body) forwards or backwards.

![Docking Peg #1](image1)

![Docking Peg #2](image2)

*Figure 28*
1.3.8. **Disposable light mats and accessories**

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

The light mat and its optic fiber cable are used to illuminate the bottom of the surgical site.

**WARNING:** Read the Instruction For Use of the light mats and the extension cords before any use of the product. In’Tech Medical 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 the extension cord and, if needed, the adaptor to plug the light mat into the light source. Below are some examples of possible configurations, depending on the type of light source.
Engaging the light mat into the blade: Carefully slide the mat through the dedicated channel inside the blade until the appropriate depth is reached (see figure below). Note that these channels aren’t available on blades that are meant for posterior access (S06ITM203)

Removing advice: To remove the disposable light mat, carefully slide the light mat out of the blade. Dispose after use.
1.3.9. *Reusable light cables and accessories*

The light cable, extension cords, and the light support are reusable.

The light cable helps to light up the wound.

**WARNING:** Read the Instruction For Use of the dual light cable before any use of the product. In’Tech Medical can’t be responsible for any misuse of the dual light cable. This Instruction for Use is included inside the packaging.

**Connection:** Plug the dual light cable to the light source or, if needed, to an adaptor. Below are some examples of possible configurations, depending on the type of light source.
1.3.10. **Shim, broach and shim/broach holder**

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

- Clip the shim (or broach) to the distal clip spring of the shim/broach holder (see picture 35). The laser marking on the shim (or broach) provides you with the correct orientation.

- Ensure that the square feature present on shim/broach is correctly engaged with the spring clip feature (see figure 36) before locking the shim (or broach) by pushing the locking cam, securing the fit (see picture 37).

- Insert the shim (or broach) into the blade dedicated slot until the suitable depth is reached (see figures below).

- Release the shim (or broach) by pushing the trigger (with the forefinger).
1.3.11. **Threaded shim and 2.5mm hex screwdriver**

The threaded shim and the 2.5mm hex screwdriver are reusable.

![Figure 40](image)

Unlike the other shim or broach, the threaded shim must not be inserted with the shim inserter. Manually engage the threaded shim from the top of the blade and slide it down to the base of the blade. Use the 2.5mm hex screwdriver to screw the threaded shim (see figure below).

![Figure 41](image)

To remove the threaded shim, unscrew till disengaged from docking point and use the hockey stick, which can engage with the tip of the threaded shim to slide out of the blade (see figure below).

![Figure 42](image)
1.3.12. **Optional blade extension**

The blade extension is reusable. It is available in several configurations (see figure below).

![Figure 43](image)

- Handling of the blade extension is similar as the shim/broach procedure (see previous chapter). Clip the extension blade with the distal clip spring of the holder.
- Make sure the square feature is fully inserted in the spring clip feature of shim inserter before locking the blade extension by pushing the locking cam forward (with the thumb).
- Insert the blade extension into the blade dedicated slot until the suitable depth is reached.

![Figure 44](image)
1.3.13. **Optional 4th blade and its support**

The 4th blade and its support are reusable.

- Clip the 4th blade attachment connectors to distal end of the retractor body, (see figure below). The arms of the 4th blade attachment can slide to match up with the retractor body opening. The connectors of the 4th blade attachment can pivot & rotate to mate with the retractor arms angulation.

*Figure 45*

- Select the suitable 4th blade (depending on the required length and width). Insert the 4th blade in the dedicated channel inside the attachment. At this point the 4th blade is still mobile: it can slide **up and down** (through the attachment’s channel), **laterally**, or even **angularly** (see figure below).

*Figure 46*
- Once the 4\textsuperscript{th} blade is in position you may lock its position by screwing the knob with the wrench (see figure below). Note that this action will prevent R\&L retractor arms from opening (or towing) any further. If adjustments are needed on retractor body, you will need to unlock the 4\textsuperscript{th} blade attachment’s knob first.

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{figure47.png}
\caption{Figure 47}
\end{figure}

1.3.14. \textit{Penfield elevator and hockey stick}

The penfield elevator and hockey stick are reusable. They can be used to tuck the tissue behind the blade, or reposition the tissue to allow better visibility or access.

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

\begin{figure}[h]
\centering
\includegraphics[width=0.3\textwidth]{figure48.png}
\hspace{1cm}
\includegraphics[width=0.3\textwidth]{figure49.png}
\caption{Figure 48 \hspace{1cm} Figure 49}
\end{figure}
1.3.15. **Bipolar forceps**

Bipolar forceps are reusable but very fragile. Refer to the dedicated Instruction For Use for more details.

Use bipolar coagulating forceps to grasp, manipulate and coagulate selected tissue.

**WARNING:** Read the Instruction For Use of the bipolar forceps before any use of the product. In’Tech Medical can’t be responsible for any misuse of the bipolar forceps. This Instruction for Use is included inside the packaging.

It must be handled with care to prevent damage. Take precautions to prevent tip breakage.
1.3.16. **Suction tube**

Suction tube is reusable. It is composed of a tube and a cleaning stylet.

![Figure 51](image)

Use the suction tube to remove fluids and residue out of surgical site. Plug the suction tube to the tubing connected to the suction vacuum. Connect the suction tube to the suction vacuum using tubing (not included in retractor kit). Remove the cleaning stylet to allow for suction. Placing the thumb on the hole at proximal end can help modulate the power of aspiration.

The cleaning stylet can be used to help clean the tube. For example, to remove residue from the tube.

It must be handled with care to prevent damage. Take precautions to prevent any breakage. Please follow cleaning instructions described in the dedicated paragraph.
1.3.17. **Contrast puck**

Place the contrast puck, also known as fluro-modulator, above the bright area to obscure it in the fluoroscopy and make the outlines sharper. The contrast puck will be used at the discretion of the surgeon.

![Figure 52](image)

**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 impact on the quality, contrast and readability of the radioscopy. In’Tech Medical won’t be responsible for any misuse of the machine.
1.3.18. **Stacking tray**

The tray is reusable. It is composed of 2 sub-assemblies:

- Each component has a specific location in the tray: use the silk-screening imprinted on each tray to rapidly identify location for storage.
- The stacking tray may be split into 2 sub-trays for ease of handling.

**Figure 53**
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 not 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 return kit for refurbishment

2.1.1. Visual inspection

Ensure 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

Ensure 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. Disassembly of the retractor body

Disassemble retractor by removing both arms, making sure the central arm is fully exposed and that the Right & Left arm locking bolts are fully unscrewed (short rod is free to move):

a. Fully unscrew the lateral nut(s) to free the short rods with the spring.
b. Unscrew large proximal knob until the central arm fully extended from body.
c. Push the left and right buttons to release both handles (see figure 54).
d. Fully screw the central nut to raise the towing mechanism on central blade

Figure 54
Areas of focus to brush and flush:

Figure 55

Figure 56

Figure 57
2.2.2. *Shim/broach holder disassembling*

Disassembly of shim/broach holder for cleaning: depress the retention tab (see figure 58), then lift the mechanism out of the track (see figure 59).

2.2.3. *4th blade attachment special handling recommendation*

The attachment must be completely opened (maximum wingspan) to maximize the access for cleaning. The screw must be loose.
2.2.4. **Dilator holder special handling recommendation**

Open the holder until the teeth on the arm are off of the rack. Use a soft brush to thoroughly clean the area between the tips, the arms, and the hinge (see figure 61).

![Figure 61](image)

2.2.5. **Table clamp base special handling recommendation**

Carefully clean the teeth of the rotative base.

![Figure 62](image)

2.2.6. **Dilators special handling recommendation**

The tip of the dilators, where the tantalum beads are inserted, must be thoroughly brushed.

Thoroughly brush the inside of both cannulae.

![Figure 63](image)
2.2.7. *Suction tube special handling recommendation*

Use the cleaning stylet to remove residue from the channel. Clean separately. Re-assemble before sterilization.

Figure 64
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).

**Both steps: manual pre-cleaning and automated cleaning are mandatory.**

**DO NOT CLEAN THE SINGLE-USE PRODUCTS.**

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. Automated cleaning

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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (minutes)</th>
<th>Temperature</th>
<th>Detergent Type and Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash 1</td>
<td>02:00</td>
<td>Cold tap water: (14.9 - 21.8°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>04:00</td>
<td>Hot tap water: (40.1 - 48.3°C)</td>
<td>Enzol® at 1 oz/gal</td>
</tr>
<tr>
<td>Wash 1</td>
<td>02:00</td>
<td>Set point 65.5°C: (65.5 - 66.4°C)</td>
<td>Prolystica® 2X Neutral at ⅛ oz/gal</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>00:15</td>
<td>Hot fully demineralized water: (47.5 - 50.2°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Drying</td>
<td>06:00</td>
<td>Set point 98.8°C: (69.2°C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- Remove each device from the washer disinfector.
### 2.4. Sterilization

Please refer to chapter 2.2.5. Table clamp base special handling recommendation 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:

<table>
<thead>
<tr>
<th>Pre-Vacuum steam sterilization</th>
<th>Gravity steam sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full cycle:</strong></td>
<td><strong>Full cycle:</strong></td>
</tr>
<tr>
<td>Sterilization temperature - <strong>132°C (270°F)</strong></td>
<td>Sterilization temperature - <strong>135°C (275°F)</strong></td>
</tr>
<tr>
<td>Sterilization exposure time - <strong>4 minutes</strong></td>
<td>Sterilization exposure time - <strong>10 minutes</strong></td>
</tr>
<tr>
<td>Dry time - 30 minutes</td>
<td>Dry time - 30 minutes</td>
</tr>
</tbody>
</table>

**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, and any other potential contamination sources. Areas with extreme temperature and humidity are not allowed.

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

For 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 expiration date.
2.6. Maintenance

According to Good Practices for instrument reprocessing, (free download at www.a-k-i.org), 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

![Retractor Diagram](image)

2.6.2. Table clamp connector

![Table clamp connector Diagram](image)
2.6.3. 4th blade attachment

![Figure 67]

2.6.4. Shim holder

![Figure 68]
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 In'Tech Medical.

In'Tech Medical 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

As In'Tech Medical is not the Manufacturer but the Foreign Exporter or Relabeller or Repackager, In'Tech Medical will forward the above required information to the Manufacturer.

2.8. Contact

In'Tech Medical
158 Rue de l’église
62180 Rang Du Fliers
France
☎ : +33 321 89 6000
☎ : +33 321 89 6009
✉ : contact@intech-medical.com

www.intech-medical.com
### 3. Chart of medical device symbols used

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image2" alt="Date of manufacture" /></td>
<td>Date of manufacture (YYYYMM or YYYY)</td>
</tr>
<tr>
<td><img src="image3" alt="Caution" /></td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td><img src="image4" alt="USA Rx ONLY" /></td>
<td>Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner</td>
</tr>
<tr>
<td><img src="image5" alt="Keep product dry" /></td>
<td>Keep product dry</td>
</tr>
<tr>
<td><img src="image6" alt="Batch code / lot number" /></td>
<td>Batch code / lot number</td>
</tr>
<tr>
<td><img src="image7" alt="Consult Instructions for Use" /></td>
<td>Consult Instructions for Use</td>
</tr>
<tr>
<td><img src="image8" alt="CE mark" /></td>
<td>CE mark</td>
</tr>
<tr>
<td><img src="image9" alt="Non sterile" /></td>
<td>Non sterile</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td><strong>STERILE EO</strong></td>
<td>Sterile EO</td>
</tr>
<tr>
<td><strong>REF</strong></td>
<td>Catalog, reorder or reference number</td>
</tr>
<tr>
<td><strong>☐</strong></td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Single use only</td>
</tr>
<tr>
<td><strong>📅</strong></td>
<td>Expiry date</td>
</tr>
<tr>
<td><strong>🚫</strong></td>
<td>Latex free</td>
</tr>
</tbody>
</table>

Symbols from ISO 15223-1:2012(F)

Leaflet: IFU17243 rev B

Date of leaflet update: 2017 Sept 21th