1. Purpose

The purpose of these Safety Guidelines is to set the standard of safety for the patient and medical personnel involved in the procedure of lithotripsy using lasers.

2. The requirements of the medical facility and medical doctor in the performance of laser lithotripsy procedures

1) Requirements of the medical facility

In order to be able to offer laser lithotripsy procedures, the facility must have all pertinent instrumentation readily available, such as the laser devices, transurethral ureteroscopes and percutaneous nephrosopes. The facility must have well-trained personnel with adequate knowledge and experience in both the requisite procedures and the handling of the devices. The facility must also have urologists filling the requirements listed below in 2), and who are experienced in transurethral lithotripsy procedures and percutaneous nephrolithotomy procedures.

The facility should be certified by the Japan Society for Laser Surgery and Medicine, and accredited as an educational facility by the Japanese Urological Association.

2) Requirements of the medical doctor

The medical doctor must be a board certified specialist of both societies listed above.

3. Adherence to the user’s manuals and appendices and the safe keeping and management thereof

All medical and paramedical personnel associated with the laser lithotripsy procedure are required to have thoroughly read the manual and user’s guide which come with the laser hardware. The facility must keep the manual and user’s guide in a safe location and have it available for reading at all times. The head of the medical facility must require the Laser Safety Manager (LSM) who is in charge of the manual and user’s guide to ensure that all users adhere to the contents of the material.

In the case of malfunction of the hardware or if the occurrence of any malfunction-related complications to the patient becomes evident, the LSM is required to report the event as an ‘adverse incident’ to the manufacturer and distributor, and to the governing agencies if necessary, using the correct forms.

4. Urinary tract stones indicative for laser lithotripsy

Lasers are used for the fragmentation of stones indicative for endourologic procedures such as TUL and PNL, the diagnosis of which are in accordance with article 1) of the Urinary Tract Stone Diagnosis Guideline.

5. Instructions for the safe performance of laser lithotripsy procedures

1) Inspection of machinery prior to treatment

Pre-operative examination (visual examination, performance checks) must be performed. Confirmation of
normal function and performance, including calibration of the laser output power are required.

Silica fibers are prone to damage, therefore a spare must always be present. A spare safety device and blast shield must also be prepared.

2) Instructions to be followed during the procedure

At the time of laser lithotripsy, the patient, doctors and all medical personnel present are required to wear protective goggles. The laser should be used and activated as dictated by the user's manual. The laser beam must be aimed at the stone itself and never at the luminal membrane. In order to safely do so, close attention must be paid to the tip of the laser fiber. Special care should be taken when using the Ho:YAG laser for the procedure, as the Ho:YAG laser is known for its potential to damage tissue. However the laser may be aimed at and used on granular tissue or at polyps near the stone at the discretion of the attending medical doctor.

Always make sure that the surgical field is amply perfused in order to prevent heat damage to surrounding tissue.

3) After the laser lithotripsy procedure

After the laser lithotripsy procedure, imagery to confirm the success of the procedure must be acquired and follow up must be performed to check for the formation of ureteral strictures in the area where the stone was lodged.

6. Informed consent

Written consent for the performance of the procedure is required from the patient after he/she has been fully informed on the therapeutic effect, risks and complications associated with the procedure.

References