INFORMED CONSENT APPLICATION ON PERCUTANEOUS LASER DISC DECOMPRESSION (PLDD) PERFORMED BY DR GIAN PAOLO TASSI

I, the undersigned, born on (date of birth)……..in (city and state)……..resident in (city and state)……..……(street and number)……
is informed in detail by Dr. Gian Paolo Tassi on the disc decompression through laser (also called PLDD). This technique was developed in the mid-80's by Prof. Daniel S.J. Choy of Columbia University in New York and the first clinical case that was treated dates back to February 1986. Before the procedure, we give the patient antibiotics (usually vancomycin and/or rocefin and/or dalacin) in order to prevent, as much as possible, the risk of infection of the intervertebral disc (discitis) and anxiety (valium). The procedure involves placing the patient in the operating room (lateral decubitus position - either left or right) and finding the needle entry point to posterolateral lumbar level or, sometimes, para-median for the space L5-S1. For cervical hernias, the entry point is located on the anterior right side of the neck along the medial margin of the sternocleidomastoid muscle and the patient is in a supine decubitus. Once you have found the entry point of the needle with a C-arm, you inject local anesthesia in that point, 3cm deep. Still with a C-arm (moderate use of x-rays), we follow the progression of the needle (from 18 G or 20 G) until it reaches the nucleus pulposus (the center of the intervertebral disc from which the disc protrusion or herniation originates). The use of local anesthesia allows you to constantly monitor, and so to preserve, the nerve root possibly grazed by the needle. Once you reach the nucleus pulposus you introduce the optical fiber (400 microns) inside the needle and start the output of laser impulse (laser machine used Nd: YAG 1064 nm or Diode 1064 nm) that is individualized as the power of an individual impulse and global energy supply. This allows you to get the vaporization of a small amount of nucleus pulposus (usually from 20 to 40 mg) as well as, in cases with positive results, to gain the decompression of the nerve root. In case there is, at this stage, the accumulation of heat towards the nerve root the patient would immediately refer (and he/she will be taught to do it, during the procedure) because we "work" under local anesthesia. The goal of PLDD is not the anatomical disappearance of hernia/protrusion (which occurs in approximately 30% of cases of patients with positive results) but the noticeable reduction of its pressing on nerve root. The selection of patients meets national and international guidelines for the treatment of disc herniation/protrusion. While performing PLDD we respect the indications and contraindications reported in paramount scientific publications, to which reference is made. Since the beginning of its use, no less than 100,000 patients have been treated with PLDD worldwide. Positive results vary, depending on the author, from 70 to 89% (my personal result is almost 85%) with complications ranging from 0.1% to 1% (my personal result 0.1%). The most frequent complication in most of the authors is discitis (infection of the intervertebral disc) that responds positively to the use of antibiotics for several weeks, rest and, in extreme cases, surgery. This complication occurs between the 3rd and 45th day, despite optimal antibiotic therapy performed before, during and after the treatment. The discitis can be cured without consequences using specific antibiotics for 4-6 weeks, resting or, in exceptional cases, with a new surgery very similar to that one used for the herniated discs. If there is the suspect of discitis, the patient must have a new MRI, blood analysis (mainly C-reactive protein – CRP – erythrocyte sedimentation rate – ESR – and white blood cells) and infectious disease specialist consultation. The symptoms of discitis are various (back pain in 86%, fever in 35-60%, loss of radicular sensibility, leg pain). For cervical hernias we need to add the risk of hematoma or latero-cervical hemorrhage which may require immediate evacuation through surgery. The possibility of relapse after PLDD is about 5% (my personal result 4%) and can occur after some time or after years (the

retractability depends on the patient). In patients with a history of "traditional" surgery (microdiscectomy or discectomy) you can often, but not always, practice PLDD but in such cases positive results have a lower percentage (my personal result 72%). Risks of complications or relapses do not change. After the procedure, the patient should observe a period of rest from work that varies from 15 to 40 days depending on the activity carried out and should resume the common daily activities very gradually. He must wear a lumbar compression garment for a period of 15/30 days. The patient has been also informed of the following: a) the positive results after PLDD may not occur immediately but they may require varying times from 1 to 10 weeks; b) in the event of failure of PLDD the use of so-called "traditional surgical procedures" is not precluded. They can be perfectly performed whereas PLDD is limited to the reduction through vaporization of a minimum amount of the nucleus pulposus of the intervertebral disc by using thin needles (diameter of 0.8 mm. or less) and thinner fibers (400 or 300 micron); (c) that a fair percentage of herniated discs or protrusions can get better spontaneously over a period of months; (d) that the "traditional" surgery (orthopaedic or neurosurgical) or endoscopic herniectomy are treatment options; (e) that in 10 % of cases with herniated or L5-S1 disc protrusion (or, more rarely, L4-L5) it is not possible to penetrate the intervertebral disc and this is verifiable only during the procedure. PLDD does not exclude a priori that the patient may have a worsening of symptoms due to an increase in volume of herniation or protrusion that can occur after the treatment (within weeks or years) not for the direct effect of the procedure but, usually, due to inappropriate efforts or traumas. The follow-up are scheduled after 10 days, 1 month, 6 months. These follow-up will be done with Mr. Gian Paolo Tassi or with Ms. Carla Cordivari (Neurologist co-operating with Mr. Gian Paolo Tassi on the PLDD service). Ms. Carla Cordivari will perform also the first consultation when Mr. Gian Paolo Tassi will be away from London.

WE KINDLY ASK THE PATIENT TO HANDWRITE HERE BELOW WITH A PEN WHAT FOLLOWS:

I, THE UNDERSIGNED, (NAME AND SURNAME) HEREBY ACKNOWLEDGE THAT I HAVE FULLY READ AND UNDERSTOOD WHAT WRITTEN IN THE AFOREMENTIONED INFORMED CONSENT. THAT I HAVE ALREADY RECEIVED THE SAME INFORMATION DURING THE EXAMINATION AND THE INTERVIEW WITH DR. GIAN PAOLO TASSI TOGETHER WITH ALL EXPLANATIONS ABOUT IT. I, UNDERSIGNED, WAS PUT IN A POSITION TO GIVE CONSENT TO THE TREATMENT (PLDD) WITH A WILL AWARE OF ITS IMPLICATIONS AND THE INFORMATION PROVIDED TO ME BY DR. GIAN PAOLO TASSI WERE ADJUSTED TO MY CULTURAL LEVEL, WITH THE ADOPTION OF A LANGUAGE THAT HAS TAKEN ACCOUNT OF MY PARTICULAR SUBJECTIVE STATE AND THE DEGREE OF KNOWLEDGE THAT I (THE PATIENT) HAS. I CONSENT TO THE EXECUTION OF PLDD ON MY PERSON BY DR. GIAN PAOLO TASSI.

Date (**at least 1 day before the procedure**) LEGIBLE SIGNATURE

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