

Notice of a preliminary market consultation for a negotiated procedure without prior publication of call for tenders for the acquisition of the service of fabrication of sensorized optical fiber applicators for laser ablation in biological tissues.

ERC "LASER OPTIMAL" Research project - Grant agreement no. 759159 – CUP D4118001020006

## 1. RECITALS

This Notice fulfils the purposes referred to in Article 66(1) of Legislative Decree No. 50/2016 (Procurement Code) and is aimed – based on the recommendations provided by the national anti-corruption Authority (ANAC) – at confirming the existence of the prerequisites that allow, pursuant to Article 63 of the Procurement Code, recourse to the negotiated procedure in question, alternatively, at identifying the existence of solutions for the design, development and construction of a device based on fiber-optic technology, able to integrate two functions: the delivery of near infrared light radiation emitted by a laser source, and the simultaneous monitoring of the temperature variation induced by the applicator in the surrounding medium. The technology required to prototype this device is based on the femtosecond laser.

# 2. SUBJECT OF THE PROCUREMENT

Politecnico di Milano intends to purchase the service of fabrication of sensorized optical fiber applicators for laser ablation in biological tissues.

To that aim, the supply should be the design, development and fabrication of a customized applicator relying on fiber optic technology, which fulfils the following non-standard requirements. The applicator should deliver laser energy with power in the range 0.5-10 W, distributed all along a defined cylindric surface ("side-firing laser fiber"), and provide, simultaneously, the temperature rise induced in the tissue, in specific regions, by mean of Fiber Bragg grating sensors (FBG). The tool should embed twofold feature: to deliver laser light for therapeutic purposes, and allow, within the same object, the real-time measurement of tissue temperature, thanking advantage from optic sensors which exploit the multiplexing function, and embedded within the same delivery fiber. The minimum desired measurement range for the sensors is 20-120 °C.

This purchase should enable the research group of Prof Paola Saccomandi to develop a prototypal device, which is not presently available on the market, thereby meeting the scientific and specific needs of the *"Laser Ablation: SElectivity and monitoRing for OPTImal tuMor removAL"* - *"LASER OPTIMAL"* (ERC-2017-STG Grant Agreement no. 759159) research group.



#### 3. MINIMUM PEREMPTORY REQUIREMENTS

In order to achieve the objectives of the ERC "LASER OPTIMAL" project, described above, the requested service must include the minimum peremptory requirements given below.

#### 3.1. General requirements

The general requirements for the requested service are:

- the "side-firing laser fiber" design, development and manufacture;
- the FBG-based measurement system design, development and manufacture;
- the total prototype system ("side-firing laser fiber" + FBG) design, development and manufacture;

#### 3.2. Specific requirements

The designed, developed and manufactured prototype device based on suitable fiber optic technology, corresponding to the requested service, must ensure the integration of the following two functions:

- i) the delivery of light radiation emitted by a laser source;
- ii) the monitoring of the temperature variation induced by the applicator in the surrounding medium.

More in detail, the requested service involves the fabrication of an applicator based on fiber optic technology. The applicator shall meet the non-standard requirements specifically required by the customer. Nowadays it is not possible to find a similar prototype on the market, so the device must be developed.

The applicator must be able to deliver medium-power laser energy (0.5-10 W) in the tissue by means of a fiber optic portion specially manufactured near the fiber free end (called "side-firing"). Fiber Bragg Grating (FBG) temperature sensors must be integrated into the described device. These sensors will measure the temperature increase induced in the medium simultaneously with the light radiation delivering. The sensors should measure the tissue temperature in the minimum range between 20 ° C and 120 ° C.

Femtosecond laser technology is required for the prototype device manufacturing. Ultra-short laser pulses (in the order of femtoseconds) create high-precision microscopic structures in optical fibers commonly used in telecommunication applications. These laser pulses are used to emit a specific laser light pattern and to generate gratings capable of monitoring temperature-related tissue parameters. The Femtosecond laser technology is able to create the gratings in customized sites along the fiber. This ability is essential to satisfy the project scientific requirements. Furthermore, the technology allows the gratings to be inscribed in the fiber without either mechanically or thermally damaging the fiber itself.



Specifically, the required applicator must have a diameter of ~ 200-600  $\mu$ m and a length of ~ 50-200 cm. The emitting portion length ("side-firing laser fiber" lenght) must be ~ 0.5-2 cm, while the FBGs inscribed in the fiber must be at a relative distance of ~ 1.5-4 cm. A minimum of 2 FBGs is required (one downstream, one upstream of the emitting portion of the applicator).

In order to perform precision machining on a standard optical fiber (low-cost telecom type) and to make it a custom applicator integrating optical sensors, so that it can meet the listed project requirements, a femtosecond laser technology with the following features is required:

- Pulse width: 10-15 s;
- Geometric precision: <20 nm;
- Glass fiber optic processing with minimal thermal deterioration, and not affecting the device performance;
- Glass fiber optic processing with minimal mechanical deterioration, and not affecting device performance;
- Entirely automated production process;
- Manufacturing quality inspection during the process;
- Possibility of producing gratings at any point of the optical fiber;
- Possibility of creating gratings able to interact differently with laser radiation in order to simultaneously perform multiple functions (emission and temperature measurement tasks).

A summary of the specific features which the final product must have is reported below:



CWG: wave guide



FBG: Fiber Bragg Grating temperature sensor

# 4. AMOUNT

The value initially estimated for the supply is € 50,000.00 VAT excluded.

As regards the service, the supplier will receive a declaration of the non-importability regime pursuant to art. 72, paragraph 3, no. 3 D.P.R. 633/1972 on 100% of the transaction amount.

## 5. ADMITTED SUBJECTS

Participation in this expression of interest is open to the Market Players referred to in Article 45 of Legislative Decree No. 50/2016.

#### 6. GENERAL AND PROFESSIONAL QUALIFICATION REQUIREMENTS

a. Lack of the grounds of exclusion referred to in Article 80 of Legislative Decree No. 50/2016;

b. Professional qualification requirements referred to in Article 83(1)(a) of Legislative Decree No. 50/2016: Registration in the companies registry of the Chamber of Commerce, Industry, Agriculture and Small Business or in the specific register if a cooperative, evincing the fact that the company carries out activity in the sector this expression of interest relates to.

For these requirements, the European Single Procurement Document (ESPD) must be drawn up.

## 7. SELECTIVE CRITERIA OF TECHNICAL-PROFESSIONAL ABILITY

The technical and professional abilities required to the provider of the requested service are the following:

- 1. Adequately documented know-how (by means of scientific publications, filed patents or patents on decision-pending status) about design, development and fabrication of optical tools and fiber optics, apparatus for optical applications, spectrometers and methods for optical systems development;
- 2. Know-how for the design, development and construction of sculpted tip assembly;
- 3. Know-how for the design, development and construction of compact and integrated singlemode multicore fiber assembly;



- 4. Ownership of technology of femtosecond laser;
- 5. Ownership of technology for the point-by-point inscription of gratings with a fullyautomated and flexible femtosecond-laser point-by-point fabrication process that can provide custom services;
- 6. Ownership of technology for the fabrication of optical structures within the optical fiber, like "side-firing laser fiber" and Fiber Bragg gratings (FBG) with non-disruptive technology (absence of thermal and mechanical damage);
- **7.** Ownership of technology for the fabrication of optical gratings for different aims within the same fiber;
- 8. Ownership of technology based on fully automated fabrication process;
- 9. Ownership of technology which allows the fabrication of gratings that can diffract the light at different angles, spatial distribution and intensity levels;
- **10**. Ownership of technology able to fabricate optical structures and tools which fulfil the minimum requirements described in the Section 3;
- 11. Ownership of know-how for physical simulation of optical structures to be fabricated in the requested service.

## 8. HOW TO APPLY AS CANDIDATE

The subjects able to meet the minimum peremptory requirements demanded and endowed with the technical-professional skills as outlined in the text of the agreement may apply as candidates by submitting:

- 1. ESPD (EUROPEAN SINGLE PROCUREMENT DOCUMENT)
- 2. ILLUSTRATING DOCUMENTATION
- 3. PROOF OF FULFIMENT OF REQUIREMENTS SET OUT UNDER POINT 7 ABOVE.

The documentation must be submitted exclusively in electronic format and may be sent in the following ways:

a) <u>pecateneo@cert.polimi.it</u>

The e-mail must bear as subject: "Application for the Fabrication of custom-made optical applicator service"

The interested market players must apply as candidates by obligatorily attaching the documentation and the ESPD (EUROPEAN SINGLE PROCUREMENT DOCUMENT).

The documentation must arrive by 12:00 AM on 31.05.2019.

Any documents received after such deadline will not be taken into account.



#### 9. ADDITIONAL INFORMATION

This consultation aims to know the market set-up, the potential competitors, the interested operators, the relative subjective characteristics, the technical solutions available, and the generally accepted contractual clauses, in order to ascertain whether they meet the real needs of the contracting authority.

The market players who apply as candidates can be contacted by the Project Manager with a view to delving more in depth into the technical solutions available for developing the service in question.

This Notice does not amount to a contractual proposal and does not in any way bind the Procuring Entity.

The Procuring Entity reserves the right to interrupt at any time, for reasons falling within its exclusive sphere of responsibility, the procedure initiated, without the requesting parties being able to press any claim.

The Procuring Entity, pursuant to the applications received and the related documentation analysed, reserves the right to invite to the subsequent negotiated procedure all the market players that reply by the stipulated deadlines and meet the requirements and criteria required under points 5, 6 and 7 respectively, as set out in the application.

Any requests for clarification of a technical nature can be addressed to the Project Manager, <u>erc-laseroptimal@polimi.it</u>.

Any requests for clarification of an administrative nature can be addressed to Mr Vincenzo Del Core E-mail: vincenzo.delcore@polimi.it.

The pre-consultation notice has been sent to the Official Gazette of the European Union on 06.05.2019

The Project Manager Graziano Dragoni