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# Clinical Follow up Plexr Report

## 1) Purpose and scope of investigation on MD Plexr (produced by the company GMV, Rome):

As part of the post-sales monitoring procedure it is conducted a review of the performance and features of the device in adversarial with the customer. The evidence gathered forms the basis for a critical evaluation of the MD for the purpose of possible improvements. In the event that the information gathered, possibly combined with other information related to the technological evolution of the market, prove essential for the purposes of clinical evaluation, it will be updated annually.

As part of the clinical follow-up procedure, as a result of the treatment, all patients enrolled in clinical investigation should be followed by the clinical contact person for a period of at least 6 months post-treatment.

The clinical investigation shown here, conducted by Dr. LAURA TEALDI (Surgeon at her own private practice) has the dual purpose of:

- Define the compliance with the technical specifications of the product, based on clinical indications provided by the manufacturer;
- Evaluate the effectiveness, practicality, the risk/benefit and safety of the MD.

## 2) Materials and methods

Use of Plexr (manufactured by the company GMV, Rome). For the non-surgical upper Blepharoplasty exceeding 3-4 sessions at a distance of at least 40 days apart. For the non-surgical lower Blepharoplasty lower than 1-2 sessions at a distance of at least 40 days apart.

As for removing pendulous fibroids, hemangiomas, xanthelasma, actinic and senile keratosis, age spots usually just one sitting.

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**Clinical assessment and results for Plexr equipment:**

| **Disease treated** *(Blemish brief description)* | **Types of patients** *(Number, sex, age range)* | **Relevant aspects** *(% Positive results)* | **Unexpected events and assessing possible causes** *(% Negative results)* | **Duration of the treatment** | **Final result** (*check-up at 6 months/1 year)* |
|---|---|---|---|---|---|
| **Non-surgical lower Blepharoplasty** | **170 patients 165 ♀ and 5 ♂ (30-75 years)** | **90% very satisfied 10% poor/null outcome** | **Stubborn marks for over 4 months in 30% of cases** | **3-4 sessions** | **Positive** Visible wrinkle/skin laxity reduction and increased skin tone, without any side effects |
| **Non-surgical lower Blepharoplasty** | **30 patients 26 ♀ and 4 ♂ (45-60 years)** | **100% satisfactory outcome** | **Redness and marks in 50% of cases** | **1-2 sessions** | **Positive** Visible wrinkle/skin laxity reduction and increased skin tone, without any side effects |

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| | | | | | |
|---|---|---|---|---|---|
| **Removal of skin marks** | **70 patients 70 ♀ (50-80 years)** | **100% positive** | **Failed to 1st intervention because deep dermal mark** | **1-2 sessions** | **Positive** Complete removal of the imperfection without the onset of side effects |
| **Removal of actinic and senile keratosis** | **40 patients 40 ♀ (60-80 years)** | **100% positive** | **none** | **1 session** | **Positive** Complete removal of the imperfection without the onset of side effects |
| **Removal of angioma** | **20 patients 20 ♀ (40-60 years)** | **98% positive** | **none** | **1-2 sessions** | **Positive** Complete removal of the imperfection without the onset of side effects |

| | | | | | |
|---|---|---|---|---|---|
| **Removal of pendulous fibroids** | **110 patients 90 ♀ and 20 ♂ (30-80 years)** | **100% positive** | **none** | **1 session** | **Positive** Complete removal of the imperfection without the onset of side effects |
| **Removal of xanthelasma** | **10 patients 8 ♀ and 2 ♂ (45-55 years)** | **90% positive** | **none** | **1-2 sessions** | **Positive** Complete removal of the imperfection without the onset of side effects |

**3) Interface arrangement with the company GMV**

The clinical reference will publish this detailed report with the evidence found; if the clinical reference detects unexpected events, he must communicate the same to the Clinical Specialist of GMV Eng. Sara Ciocca, who will assess with their collaboration if such evidence should lead to a revision of the analysis of risks and/or changes to the MD.

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The document references *Risk Management File Plexr.pdf are shown below*:

## 2. CHEMICAL - BIOLOGICAL HAZARDS AND CONTRIBUTING FACTORS

*(Bio-contamination - bio-incompatibility - incorrect formulation - toxicity - allergenicity - mutagenicity - oncogenicity - teratogenicity - carcinogenicity - re-infection and/or cross-infection - pyrogenicity - inability to maintain hygienic safety - degradation)*

| **2** | **DANGEROUS PHENOMENON (Source risk)** | **SEQUENCE OF PREDICTABLE EVENTS** | **DANGEROUS SITUATION (Consequence)** | **DAMAGE** |
|---|---|---|---|---|
| **A.** Using material harmful to the patient | | ▪ Non bio-compatible material used in contact with the patient<br>▪ Material containing phthalates | ▪ Handpieces and accessories made from non bio-compatible material | ▪ Irritation and allergic phenomena to the patient |
| **B.** patient infection for use of contaminated accessories | | ▪ handpieces contamination<br>▪ use of non-sterile needle<br>▪ improper packing | ▪ use of contaminated accessories in contact with the patient | ▪ patient infection |

## 4. HAZARDS RESULTING FROM IMPROPER OUTPUT OF ENERGY AND SUBSTANCES

*(Electricity - radiation - volume - pressure - supply of medical gases - supply of anaesthetic agents)*

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| 4 | DANGEROUS PHENOMENON (Source risk) | SEQUENCE OF PREDICTABLE EVENTS | DANGEROUS SITUATION (Consequence) | DAMAGE |
|---|---|---|---|---|
| Electricity | | | | |
| **A.** electric current emission patient out of tolerance | | Component fault<br>Poor environmental conditions<br>First system failure | Control system failure<br>Ineffective treatment | ▪ Patient injury<br>▪ Ineffective treatment |

## 2. HAZARDS ARISING FROM FUNCTIONAL FAILURE, MAINTENANCE AND AGEING AND CONTRIBUTING FACTORS

*Transfer of incorrect data - lack of specifications or inadequate specifications for maintenance - improper maintenance - lack of proper determination of the end of life of the medical device - electrical/mechanical integrity loss - inadequate packaging - re-use and/or improper re-use - deterioration*

| 7 | DANGEROUS PHENOMENON (Source risk) | SEQUENCE OF PREDICTABLE EVENTS | DANGEROUS SITUATION (Consequence) | DAMAGE |
|---|---|---|---|---|
| **B.** Inadequate cleaning (Maintenance) | | ▪ Using aggressive agents that can ruin parts of the equipment | ▪ Equipment damage<br>▪ Patient infections through accessories | ▪ Equipment surface alterations<br>▪ Patient infection (see point 2 risk analysis) |

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**4) Benefit/Risk assessment**

The clinical study showed that the risks assessed during the analysis of the risks and associated with the use of the device are as follows:

Irritation and allergic phenomena to the patient

Patient infection

In clinical practice these are unlikely.

The treatment of 450 patients by the use of the medical device Plexr did not cause the onset of any adverse event.

So the device is believed to be effective and safe for clinical applications assessed in the present study and intended by the manufacturer GMV Srl

Signature and stamp of the doctor

Dr. Laura Tealdi