Informed consent to medical treatment in pediatric dentistry: a proposal for two new model forms for the public health care system

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Summary

Over the last years, case-law and doctrine have increasingly focused on informed consent to medical treatments. This sensibility derives from the newly achieved awareness about the implications of the right to health and of the true interests underlying informed consent. Another reason is the ever-increasing litigation on the adequacy and correctness of the preliminary information given for medical treatments. Between 2008 and 2011 only, the Italian Supreme Court has ruled over a number of medical-liability cases that was equivalent to those decided during the decade 1991-2000, higher than all the judgments issued during the period 1942-1990. Among medical disciplines, also dentistry has been characterized by a meaningful increase in malpractice claims, from 3.6% in 2003 to 9% in 2010. In all those instances, inadequacy of preliminary information is one of the main arguments used by patients for their claims against health-care operators. The relevance of informed consent for dental treatments and therapies thus becomes apparent, both in relation to patients' awareness and for the legal protection of operators. The model forms attached to this publication have been developed keeping these factors in mind. The forms distinguish themselves for the possibility of customization and have been developed to fully support doctors in their preliminary communication with patients, before performing the medical treatment requested.

Key words: pediatric dentistry, legal medicine, informed consent.

Introduction

Informed consent is an expression coined by the California Court of Appeal in 1957, in the "Martin Salgo *vs*. Leland Stanford University" case. The ruling highlighted – for the first time – the importance of informing patients about the nature, risks and consequences of surgery execution, in order to ensure their fully aware decisions. The principle of the necessity of adequate preliminary information in order to acquire a legally valid consent was thus born. In the "Natason *vs*. Kline" case (1960), the Kansas Supreme Court chose to adopt the Salgo doctrine and specified that the necessity of preliminary information was founded on the principle of self-determination, according to which any person has the right to choose his destiny autonomously and consciously, provided he is sound of mind. In Italy, medical liability for defective or omitted acquisition of consent became relevant in the Nineties, thanks to the Massimo case (Cass. Pen., Sent. n. 5639/1992). In that occasion, the Italian Supreme Court condemned a surgeon for manslaughter, due to his arbitrary and imprudent conduct while performing surgery, without previously acquiring the patient's necessary consent. A detailed analysis of the Italian Supreme Court's case-law on the topic shows that it mainly rests on the inviolable principles of individual freedom (Art. 13 of the Italian Constitution) and protection of health (Art. 32 of the Italian Constitution). Based on the relevance of the above interests, the Italian Supreme Court has specified that informed consent constitutes a legal prerequisite for medical activity. For this reason, in case of dissent or absent a patient con-

sent, and save when either Art. 54 of the Italian Criminal Code or mandatory medical measures are applicable, no health-care therapy or treatment is admissible. Furthermore, by the same token, consent can be deemed valid only when resulting from a dialogue with the competent doctor. The latter has to provide a full disclosure about the diagnosis, prognosis, risks, possible therapy's side effects and their gravity. This information must be adequate to permitting patients to choose between possible alternative treatments, to refuse or interrupt therapies; the relationship between doctors and patients is based on the principle of freedom of choice by patients with regard to their own health, provided that they are sound of mind. Patients' decision must be respected by the medical personnel, and no person has the right to cure someone else (Cass. Pen., Sent. n. 37077/2008; Cass. Pen., Sent. n. 11335/2008). In accordance with the above arguments, the Code of Medical Ethics states that "Doctors shall not begin or continue any diagnosis or therapy without the preliminary acquisition of informed consent or in case of informed dissent" (Art. 35, par. 2 of the Code). From a deontological perspective, informed consent is, above all, a moral duty, and only then a legal duty (1). Doctors who are respectful of their patients' dignity know that their personal view cannot replace a patient's decision, but only help his assessment.

The proposal for two new model forms

The proposed model forms attached herein (Attachments A and B) for the acquisition of informed consent, developed by the Pediatric Dentistry and Odontostomatology UOC of the Rome "Umberto I" University Polyclinic, derive from the necessity to ensuring medical activities stay focused on patients, at the same time safeguarding medical personnel and health care facilities. Furthermore, also the specific needs of persons mentally disabled have been expressly considered. In these cases, the patients' conditions often require general anesthesia and to concentrate more operations in just one sitting. To this purpose, Attachment A has been developed to include a detailed list both of specific dental treatments, and of information integrating those verbally provided by doctors. The written form, although not mandatory, is always to be preferred for a number of reasons: a) to consent patients and their legal representatives to consult treatment modalities and relating risks at any time, thus permitting possible revocations of the consent previously given; b) to better highlight the gravity of the possible risks and the therapy goals; c) to offer medical personnel an easy-to-read instrument able to integrate and guide the information provided verbally; d) to safeguard the personnel by reducing the risk of performing treatments not supported by patients' clear authorization. The same rationale underlies the new form (Attachment B) for the acquisition of consent to orthodontic therapies. However, this document is less technically detailed, since it aims at focusing patients' attention on the therapy goals and the need of cooperation with doctors. From a theoretical point of view, the modern and more agreed upon criterion to identify the information adequacy for consent is a subjective standard. Under this standard, doctors must communicate with patients based on the latter's cultural and social level, so that they can fully understand their clinical situation and decide accordingly (2). In this regard, it has been specified that the principle of correctness underlying any doctor-patient relationship should mandate that information is provided loyally and clearly, in a simple and straightforward way. Corollaries of the principle of correctness are the principles of reasonableness and adequacy of information. The former is a standard to individuate the boundaries of the duty to inform; only risks that can be considered typical (i.e. statistically likely), based on the clinical situation, should be communicated. Pieces of information that are superfluous for a patient decision should not be considered subject to a disclosure duty, especially in light of the fact they may hamper a patient's decision process (3). However, it must be pointed out that, according to the Italian Supreme Court, also risks that are merely foreseeable should be communicated when they can seriously affect patients' health or lives (Cass. Civ., Sent. n. 9374/1997). In light of the above context, the latitude of the information duty – especially in relation to the risks involved – has been addressed with different intensity in the model forms attached. In Attachment A, which has been tailored for patients with disabilities who require general anesthesia, also risks that are statistically less frequent have been included. However, the possibility for doctors of further customizing the information has been preserved. In particular, we have set forth some special sections (e.g. Sections A to D of paragraph 3.2.3 of the form) in order to clearly differentiate each dental sector and the relating typical risks, thus ensuring an extremely detailed and precise information, both from a stylistic and technical point of view. In doing so, we have aimed at focusing patients' attention on the relevant risks, while limiting unnecessary information. In Attachment B, which has been developed for orthodontic treatments during pediatric age, the information especially regards the therapy and treatment goals, as well as the importance of patients collaboration. In particular, since the purpose of these treatments is to usually achieve a proper occlusion in a harmonic face, the information has been structured by looking to the functional aspects of the operations rather than to the esthetic ones. This clarification is especially sensible when we consider that information – inducing a patient to believe he will surely attain a specific esthetic result – may be a source of legal liability for orthodontists, in the event the promised results are not achieved (Cass. Civ., Sent. n.

16394/2010). The same liability may arise also when sufficient information – about risks and factors preventing the hoped treatment results – is not provided. In all these cases, orthodontists will be held accountable if the undisclosed risks or factors materialize, even when they do not depend from their personal actions (Cass. Civ., Sent. n. 7237/2011). In any event, the duty to inform is not exhausted by just delivering and signing the forms for consent acquisition. It must be remembered that they have an integrative function of the verbal exchange with medical professionals, and that – in particular – they emphasize the importance of the decisions to be taken, since they are the conclusion of a "diagnostic procedure or therapeutic treatment that may seriously affect a person's safety" (Art. 32 of the abovementioned Code of conduct). The standard of adequacy for the information provided cannot be deemed satisfied by simply acquiring a patient's signature to a "dedicated form", since it must appear with certainty that the patient was specifically informed about all the relevant risks and factors connected to the relevant medical treatment (Cass. Civ., Sent. n. 24791/ 2008) (4). However, the availability of a written form is crucial to easing a party's burden of proof in case of litigation. Clearly on the point, the Italian Supreme Court has stated that "the exclusion of any liability can be founded, […] rather than on witnesses' declarations and technical legal assessments, on the signatures made by a patient in his medical records, according to which he formally acknowledged to accept the anesthesia and the prescribed treatment and therapy" (Cass. Civ., Sent. n. 17157/ 2007). As explained above, Attachment A has been developed for patients with cognitive disabilities. Their frequent lack of cooperation during the operations can especially make the diagnosis phase extremely difficult. In turn, this circumstance affects how the patients' consent can and should be acquired. The experience obtained on the field has permitted to crystalize those modalities into Attachment A, which summarizes the main dental operations – carried out in regime of general anesthesia and in operating room – in a single document, which can be included in the medical records, thus simplifying the efficient management of patients' documentation. The model form in Attachment A thus ensures a helpful instrument, and a high level of clarity, precision and completeness of the information provided, as well as a reliable written proof of the truly "informed" nature of the consent acquired. It should be pointed out that certain paragraphs (1.5.; 2.6.; 3.2.7.) require special attention and sensibility from operators during the consent acquisition phase, especially because they are applicable only under specific conditions and for treatments provided after general anesthesia. A symmetric approach has been used in structuring Attachment B, which – however – characterizes itself for being divided into two parts, a diagnostic and a therapeutic one, in order to better support the operators. A list of the most frequent dental pathologies and operations encountered in the public health care system is provided, together with special blank slots for apposite further integrations. As clarified above, the focus is on the operations' goals and on their potential results, rather than on the description of the instruments used. To ensure the correctness of the information provided and to avoid undue expectations from patients (which may result in litigation), more emphasis has been given to the possible variability of the dental-treatments outcomes. For the same purposes, more attention has been dedicated to the duration of therapies and the need for patients' cooperation. Both elements have been found to constitute the main causes of dental litigation (5). In particular, Attachment B highlights that the duration of therapies cannot be determined with absolute certainty, but, on the contrary, is strictly dependent on the tissues' natural response to dental operations. This is to avoid the formation of misled expectations by patients, for which orthodontists may be held accountable, even when their activity was properly performed. The same argument goes for the patients' need to cooperate and abide the medical instructions provided in order to ensure the successful outcome of dental operations. In this regard, Art. 1227 of the Italian Civil Code, which sets forth the principle of contributory negligence, plays a fundamental role. If a patient does not follow medical instructions diligently, it is him that will be held accountable, totally or partially, for the possible treatment failure. However, when medical instructions and information provided are defective, so that a patient does not realize the real extension of its cooperation duty, health care personnel will still be fully liable for any failure. Special attention must be dedicated to patients with mental disabilities. Also in these cases, the general rule is the voluntary nature of treatments. As a consequence, the participation of this kind of patients should always be ensured. However, under Art. 357, 424 and 405 of the Civil Code, it should be remembered that legal guardians can be the preferred interlocutors of doctors (see Cass. Civ., Sent. n. 21748/2007). This is because, when the health of a mentally disabled person is at risk, the complete substitution of his will with the decisions of the guardian becomes admissible, as long as the disabled's best interest is pursued (Cass. Civ., Sent. n. 5652/1989).With special reference to persons under age, it must also be kept in mind that informed consent must be given by both parents, by virtue of their parental rights (Art. 316, comma 1, c.c.), unless one of them is incapacitated (see Art. 317, par. 1). Furthermore, the joint exercise of parental rights is still necessary in the event of separation or divorce (Art. 317, par. 2 of the Civil Code), but in these cases, for minor health issues, parental rights may be exercised by each parent autonomously (see Art. 317-quarter, par. 3).

Based on this legal framework, some have distin-

guished between routine dental treatments (usually not invasive) and treatments potentially damaging minors' health. Only the former may be authorized autonomously by the parents (6).
However, a specification should be made. Minors still have to participate to the care of their health, to the extent it is within their capacity and maturity. Art. 35, par. 2 of the Code of Medical Ethics states the importance of this participation: "doctors shall keep into adequate account the minor's will in relation to all the processes that affects him". This is also confirmed by the case-law, which specified that, in relation to a minor's personal-life aspects, parental rights diminishes proportionally to the minor's awareness and maturity, especially when he comes close to adulthood (Tribunale dei minori di Milano, Decreto 30.3.2010)
In this regard, literature has individuated 3 age phases (7). In particular, under 14 years old, it is commonly agreed that parents should be able to decide about medical treatments, independently from their children's will. The latter's decision would be relevant only after the age of 14, when any explicit dissent from the minor should prevail over any contrary decision of the parents. In any event, for the purposes of informed consent and in light of the treatments listed in the proposed model forms attached, we would invite health care personnel not only to acquire the consent of both parents, but also to involve the minors in the decision process, by clearly providing them with the necessary information, especially when it appears they have a sufficient level of maturity.

A diligent use of the proposed forms for informed consent

The fiduciary relationship between doctors and patients requires the former to provide an adequate information to ensure an effective exercise of the latter's right to self-determination. To this purpose, it should be avoided that, through the forms, the acquisition of informed consent becomes a mere bureaucratic procedure or just a preventive means of legal defense for doctors. Informed consent, in fact, springs from the need to valorize medical relationships and not to further burden them. In this respect, part of the literature has stressed that informed consent is an ethical act aimed at protecting patients, and not an instrument of legal strategy to be deployed in legal proceedings (8). That is why no type of forms may ever fully replace a true information exchange at the end of the health care personnel. Written forms can have just an integrative and probationary function, which comes into play just at the end of the doctor-patient dialogue.
The best defense against charges for medical malpractice is thus a proper conveyance of all the necessary information, together with the respect of the applicable best practices. On the contrary, little or no importance at all has the aseptic provision of generic and sloppy forms for authorization. This has been clearly stated by the case-law, which has underlined the insufficiency of "boilerplate forms", where patients just declare to have been informed about unspecified treatments. Synthetic, undetailed and generic information does not suffice. Forms must report, in a specific and precise way, the specific treatments, the relating risks and advantages, as well as any ancillary measure that may be necessary to ensure a successful outcome (Trib. Milano, 24.3.2005, GD, Il Sole 24 Ore, Responsabilità e risarcimento. 2005:75).
Vague forms that completely lack precise references (also to the persons providing the information) have been deemed radically inadequate to prove, even in the slighest, the existence of a sufficient level of awareness by patients, even when they have signed those forms (Trib. Forlì, Sent. n. 209/2007). Based on the above, the proposed model forms provide a customization possibility, to tailor medical information around the patients' conditions and situation. This does not exempt doctors from answering to specific questions by patients, but helps them to carefully manage the consent acquisition process. At the same time, the forms constitute a useful paper record of that process, during which doctors have the specific task of selecting the correct and relevant information for their patients. According to an analysis of the Journal of American Medical Association, in medical malpractice cases, the probability of litigation diminishes drastically when more than 18 minutes are dedicated to the dialogue with patients, while it sensibly increases for timespans under 15 minutes (9). In particular, other surveys – specifically focused on the US dental sector – showed that the main cause of litigation (47%) was related to a poor information exchange between dentists, assistants, patients and parents (10).

Conclusions

Understanding patients' needs and providing reasonable and correct information are the foundations of a proper doctor-patient relationship. From a legal perspective, these foundations are rooted in the constitutionally protected interests of human dignity, health care and right to self-determination. Informed consent is premised on those values and becomes a prerequisite of therapies' legitimacy. There is no legitimacy when patients cannot make an informed decision based on what they have been told by the competent health care personnel. As a consequence, managing the consent acquisition process can be a complex activity, full of implications under several aspects, professional, deontological and legal. This is especially true for those operating in the public health care system, often congested by the sheer number of patients.This is the reason why the Pedi-

atric Dentistry and Odontostomatology UOC of the Rome "Umberto I" University Polyclinic has developed the proposed model forms for informed consent attached herein. These models are not a substitute for a real doctor-patient dialogue but aim at being a useful guide and tool to diligently manage the informative process, thus supporting both doctors and patients.

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Attachment A

DECLARATION OF RECEIVED INFORMATION AND CONSENT TO DENTISTRY THERAPIES

I, the undersigned ……..... (CF……...)
as □ parent □ legal tutor of ..... (CF……...)
already fully informed on prescribed therapies during the verbal interview with the medical staff of Paediatric Dentistry and Odontostomatology Complex Operative Unit, in full awareness, consent to the application of the operations indicated below:

1) CONSERVATIVE TREATMENT

□ **1.1.)** conservative treatment for the medication of carious lesions and subsequent filling with dental composite resins. Reconstruction in composite materials offer an excellent aesthetic result, however the chemical and/or physical properties of such material limit its integrity through time (low mechanical resistance to wear; porosity, decolouration and progressive dyschromia). The recurrence of caries upon previously treated areas is possible.

□ **1.2.)** conservative treatment for the medication of caries and subsequent restoration through use of metal alloys with high aureus or ceramic content (inlays). Restorations in gold alloys offer excellent precision in marginal adaptation, accurate replica of occlusal morphology, high resistance to wear on occlusal surface and lower rates of carious recurrence. Ceramic restorations offer superior aesthetic results, however suffer a higher probability of fracture, compared to other techniques; difficulty in post-application modification and in some circumstance: inability to repair the artefact.

1.3.) In the present case the following dental elements are treated: ……

1.4.) RISKS AND CONTRAINDICATIONS OF PRESCRIBED THERAPIES:

sensitivity to used materials; contact allergy leading to stomatitis, lichenoid eruptions, contact allergy to rubber dental dam leading the dermatitis.
I declare to have been fully informed by the doctors whom have performed the survey and have understood all the risks and cons also indicated in paragraphs 1.1 and 1.2.
I further declare that all explanations have been given to me verbally by the doctors.
I am fully aware that the mentioned risks include the most common inconveniences related to conservative therapy; any further and more detailed information has been given to me by the medical personnel in relation to my specific case.
I am aware to the fact that failure to deal with carious lesions may lead to inflammatory lesions of the pulp with subsequent necessity of endodontic treatment or extraction of involved teeth.
I am also aware that the risk to develop further caries on additional teeth increases with the number of untreated caries.

□ **1.5.)** Therefore, I authorize, when the patient needs general anaesthesia for the reasons given in section 4.2 and at the conditions specified and agreed during the visit (evident destruction of the hard tissues of the tooth with possible manifestation of inflammatory processes of the pulp):

□ **A)** at the execution of endodontic treatment of teeth specified in paragraph 1.3 (I have been fully informed by medical personnel of the benefits and risks of such treatment; I declare that the consensus for endodontic treatment has been formed after having carefully read chapters 2 and 3 of the present module)

□ **B)** at the extraction of the teeth specified in paragraph 1.3 (I have been fully informed by medical personnel of the inability/inappropriateness to preserve such dental elements and of the risks linked to dental avulsion. I declare that the consensus for the extraction has been formed after having carefully read paragraph 3.2 of the present module)

I authorize, eventually, also outside the above conditions,

□ **C)** the execution of conservative therapies on dental elements different than the ones specified in paragraph 1.3 when, as a result of the examination of the oral cavity, performed by the medical personnel during treatment, it should turn out that further teeth are affected by caries.

Signature of the legal representative of the patient

X ……

2) ENDODONTIC THERAPY

□ **2.1.) Root canal treatment**
Endodontic therapy aims to resolve pathologies linked to the tooth pulp through cleansing, shaping and sealing of the root canal. The intent behind the therapy is to preserve the dental element.
In the present case, root canal treatment is necessary for the presence of: □ **A)** carious lesions not allowing for an efficient and valid preservation through simple conservative means; □ **B)** traumas which have damaged the dental pulp; □ **C)** Periapical lesions affecting the dental support tissues; □ **D)** Other reasons
.....
.....

2.2.) The following teeth are involved and will be acted upon: .....
.....
.....

2.3.) RISKS AND CONTRAINDICATIONS OF PRESCRIBED THERAPIES

The devitalization of a tooth is a safe procedure to enact. However, being a surgical procedure, it is not exempt of possible complications, such as: incomplete filling of the root canal and therefore need to re-operate; apical overfilling and over-instrumentation; equipment fracture within the root canal; failure to treat accessory canals and need to re-operate; root or furcal perforation; zipping; ledging; contact allergy to rubber dental dam leading the dermatitis.

Further risks may subsist if the treated teeth are situated in:
□ **A) upper-lateral-posterior sectors. Endodontic treatment on such elements may entail:**
- development of inflammatory response when external material (filling, solutions utilized during treatment) enter the maxillary sinus through a perforation;
- sinusitis of the maxilla consequent to a oro-nasal communication subsequent to a perforation of the sinus membrane by a failed filling attempt**.**

In the present case, through examination of the pre-operatory radiographies, we can assess that:
.....
.....
.....;

Further risks and clarifications:
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.....
.....
□
□ **B) inferior-lateral-posterior sectors.** In such case the biggest risk is represented by possible damage to the inferior alveolar nerve (with subsequent paraesthesia, anaesthesia, hypoesthesia and related algic symptomatology).
The risk for mentioned neurological lesions is relative to the anatomical relation between the nervous tissue and dental root. In this specific case we can assess that:
.....
.....

Further risks and clarifications:
.....
.....
.....

2.4.) I declare to have been fully verbally informed by the medical personnel whom have done the examination of the aforementioned risks; I further declare to have fully understood the implied risks thanks to the complete explanation provided by the doctors.
I am aware that risks persist despite the most scrupulous observance of the precautionary rules and in accordance with the best practice.
I am fully aware that the mentioned risks include the most common inconveniences related to endodontic therapy; any further information has been given to me by the examining medical personnel in relation to my specific case.
I have also been informed of the possible recurrence of periapical lesions despite the success of the operation and further agree to possible re-operations.
Medical personnel have also informed me of the increased fragility of treated teeth and gave me instructions as to decrease the risk of fracture.
I am aware that a restorative phase will follow a successful endodontic treatment which can consist of root-canal cores in metal or carbon/glass fibres.

For this purpose, I declare that I have carefully read paragraphs 1.1, 1.2 and 1.4 of this form and understand the risks and benefits of the treatments indicated therein. I have been informed that the non-treatment of inflammation involving pulp tissue may evolve in alveolar granuloma or abscess with consequential need to subject the patient to additional interventions to solve the disease.

2.5.) The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after the evaluation of the following alternative therapies:
……
……

2.6.) I authorize as well, when the patient receives the medical treatment under general anaesthesia for one of the reasons marked in section 4.2. and also occur the conditions discussed during the visit (impossibility to solve the ailment by orthograde methods) the:
□ **A)** execution of endodontic-surgical techniques – apicoectomy – on the dental elements specified in paragraph 2.2 (I have been fully informed by medical personnel of the benefits and risks of such treatment; I declare that the consensus for endodontic surgical treatment has been formed after receiving verbal explanation of risks and benefits and having carefully read chapter 3 of the present module)
□ **B)** extraction of the teeth specified in paragraph 2.2 (I have been fully informed by medical personnel of the severity of periapical inflammation and the inability/inappropriateness to preserve such dental elements and of the risks linked to dental avulsion. I declare that the consensus for the extraction has been formed after having carefully read chapter 3 of the present module)

Signature of the legal representative of the patient

X ……

3) ORAL SURGERY

□ **3.1.) Endodontic surgery.** Apicoectomy is necessary when the dental pulp undergoes alteration due to trauma or carious infection and cannot be treated through orthograde means (devitalization).
In the present case, surgical therapy is indicated because of: **A)** □ physical impediments of iatrogenic nature (root cores, broken instruments of difficult retrieval) **B)** □ calcification of the root canal, impeding orthograde passage **C)** □ repeated failure of the orthograde **D)** □ other (specify)
……
……
……

In the present case, affected dental elements to treat are:
……
……
……

3.1.1.) RISKS AND CONTRAINDICATIONS OF PRESCRIBED THERAPIES:

pain and swelling of the treated area; faint and sporadic bleeding of the gums; difficulty in chewing; general soreness on the side of the face where the operation took place; teeth adjacent to the treated element might be affected by the stress of the operation; infection due to bacteria colonization of the suture with subsequent problems in wound healing (this risk can be mitigated by following with attention indications given by the medical staff).

3.1.2.) Further risks may subsist if the treated teeth are situated in:
□ **A) upper-lateral-posterior sectors.**
Endodontic surgery treatment on such elements may entail
• sinusitis of the maxilla consequent to a oro-nasal communication subsequent to a perforation of the sinus membrane.
In the present case, through examination of the pre-operatory radiographies, we can assess that:
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Further risks and prescriptions:
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□ **B) Inferior-lateral-posterior sectors**
In such case the biggest risk is represented by the damage to the inferior alveolar nerve (with subsequent paraesthesia, anaesthesia, hypoesthesia and related algia symptomatology).
The risk for mentioned neurological lesions is relative to the anatomical relation between the nervous tissue and dental root. In this specific case we can assess that:
……
……

Further risks and prescriptions:
……
……

3.1.3.) I declare to have been fully verbally informed by the medical personnel whom have done the examination of the aforementioned risks; I further declare to have fully understood the implied risks thanks to the complete explanation provided by the doctors.
I am aware that risks persist despite the most scrupulous observance of the precautionary rules and in accordance with the best practice.
I am fully aware that the mentioned risks include the most common inconveniences related to endodontic surgery therapy; any further and more detailed information has been given to me by the examining medical personnel in relation to my specific case.
I declare, when sections 3.1.2, points A) and/or B) are selected from the module (risks of endodontic surgery in the posterior, upper and/or posterior, lateral and inferior sectors), that consent to the interventions was formed thanks to the explanation of the related risks and benefits and, in any case, after reading also paragraph 3.2.3. points A) and C).
I have also been informed of the possibility that the periapical lesion persists even in the case of a successful operation.
I declare to be aware of the possibility to subject the patient to a new radiological investigation and to a possible re-intervention for the extraction of the involved dental elements (I am also aware that in this case prosthetic rehabilitation may be required).
I am aware that the non-treatment of the diagnosed pathology can result in a worsening of said condition and subsequent extraction or needing of more invasive treatments.

3.1.4.) The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after the evaluation of the following alternative therapies:
……
……

□ **3.2.) Dental extraction**
Extraction of teeth is indicated when the presence of said teeth is counterproductive to the wellbeing of the oral cavity and, more generally, of the patient. In the present case, extraction is indicated for:

A. □ **carious lesions** who impede a correct restoration of the crown/root using either conservative or prosthetic techniques;
B. □ **periodontal pathology** which caused loss of the supporting tissues around the tooth/teeth with impairment of masticatory function;
C. □ **endodontic lesion** determining inability to treat the tooth with the techniques referred to in chapter 2 and paragraph 3.1. of this form due to previous failure of therapies or due to an adverse general/local;
D. □ **tooth/root fracture** with unfavourable prognosis, or presence of vertical fractures;
E. □ **roots unable to be recovered** prosthetically or root residues;
F. □ **impacted or semi-impacted teeth** non-recoverable through surgery, orthodontic or conservative means;
G. □ **supernumerary teeth** with aberrations such to not recommend preservation;
H. □ **supernumerary teeth** in retro-incisal position. The avulsion is indicated as to avoid: diastemas, obstruction of the normal eruption of permanent teeth, dislocation and/or rotation of adjacent teeth, coronal or root reabsorption, malocclusion, symmetry alterations, dental crowding, ectopic eruption;
I. □ **orthodontic treatments** in which extraction is part of the therapy (for spatial reasons) or for the realignment of the remaining teeth;
J. □ **lesions** on teeth next to shedding on which any conservative therapy will be inconvenient;
K. □ **prenatal teeth** which can cause disturbance to breastfeed;
L. □ **primary teeth causing obstruction** or difficulties in the normal eruption scheme of permanent teeth;
M. □ **residues of primary teeth**. The extraction is crucial to avoid the stimuli to inflammatory and flogistic lesions deriving from bacteria colonization;
N. □ **dysodontiasis** (difficulty in the eruption of dental elements, commonly due to lack of suitable space or incorrect orientation of the tooth);
O. □ **medical or surgical conditions** for which extraction as prophylaxis is required;
P. □ **periapical** or **periodontal** lesions in subjects who must undergo radiation therapy of the jaws;

Q. 1. □ **other**; 2. □ Details on the reason of the extraction
……
……
……

3.2.1.) In the present case, extraction is required for the following teeth
……
……
……

3.2.2.) COMMON POST-OPERATIONAL DISORDERS AND PATHOLOGIES RELEVANT TO ALL DENTAL AREAS

Leaving aside the specific area of operation, every extraction could entail:
- pain and swelling of the treated area; faint and sporadic bleeding of the gums; difficulty in chewing; general soreness on the side of the face where the operation took place;
- bleeding for prolonged time or even much after the end of the operation, usually controllable with simple compression with a sterile gauze;
- hematoma, which can extend in periorbital area or below in the superficial neck area due to blood extravasation in the submucous tissues (in case of more extensive hematomas antibiotic prophylaxis and evacuation through needle aspiration may be required);
- ecchymosis (subcutaneous blood collection; does not require, except in the most serious cases, interventions for its resolution);
- infection of the post-extraction wound due to bacterial colonization of the site (this risk can be mitigated by following with attention indications given by the medical staff, risk is higher with smoking patients);
- lesions to adjacent teeth, more frequently if said teeth have big restorations or suffer from advanced periodontal pathology;
- alveolar abscess (complication favoured by the penetration of food residues in the post-extraction alveolus). It is characterized by a painful edema and exudation of purulent serum with possible presence of fever; it requires antibiotic therapy and alveolus cleaning;

Further risks or details:
……
……
……

3.2.3.) RISKS AND CONTRAINDICATIONS OF THE PRESCRIBED THERAPIES FOR SPECIFIC DENTAL SECTORS

In this specific case the extractions involve teeth situated in:
□ **A) LATERAL-POSTERIOR SECTORS OF THE JAW**
When the operation involves elements collocated in such areas possible outcomes include:
- pain and swelling of the treated area; faint and sporadic bleeding of the gums; difficulty in chewing; general soreness on the side of the face where the operation took place;
- subcutaneous or submucous emphysema due to the use of high velocity rotating instruments used in odontomy;
- lockjaw (spastic contraction of the masticatory muscles of the jaw which impede normal movements) typically present after extracting third molars with particular intra-operatory difficulties;
- alveolar osteitis (painful inflammation which can lead to radiating pain to head and neck, due to the dissolution of the blood clot and exposition of the alveolus);
- fracture of opposite teeth for loss of control of the instruments for extraction, or if the tooth yields to stress, or in case of loss of grip on the tooth/root;
- dislocation of the tooth, or parts, inside the mandibular canal;
- dislocation of the jaw caused by movements and/or tractions performed during tooth avulsion (repositioning of the jaw and rest may not suffice for a complete recovery; a specialist approach may be necessary);
- lesion of the inferior alveolar nerve or of the lingual nerve with possible loss of sensibility both partial or definitive (problematic tied especially to extractions of the inferior third molars). The risk of neurological injury depends on the relationships between the nervous structures and the roots of the extracted teeth.

In this case, from pre-operative radiological examinations it appears that: (describe relation between roots and nervous structure):
……
……
……

Further risks or details:
……

□ **B) ANTERIOR SECTORS OF THE JAW**
The extraction of teeth located in this sector may lead to:
- discomfort in aesthetic and phonation; displacement of adjacent teeth; bleeding; fracture or loss of contiguous elements, especially in the presence of previous pathologies affecting the supporting tissues of the teeth.

Further risks/clarifications:
……
……
……
□
□ **C) UPPER-POSTERIOR-LATERAL SECTORS**

The extraction of teeth in this sector may lead to:
- dislocation of the tooth, or parts, inside the sinus cavity with possible development of inflammatory response. Therapy may require the surgical retrieval of the dislocated mass;
- bleeding (profusely in case of damage to major blood vessels;
- osteitis of the maxilla (infection due to septic response in the alveolus or due to bone trauma, may require antibiotic therapy and alveolus surgery);
- sinusitis of the maxilla (complication usually linked to the extraction of upper molars or premolars). The risk is associated to the thickness of the bone separating the roots and the sinus membrane (which varies amongst patients). The operation may lead to perforation of the sinus membrane or removal of said bone, leaving the sinus exposed and possibly causing an oro-nasal communication with a chance of contamination linked to possible infectious material entering the sinus (therapy may include a surgical approach to close the communication).

In this case, from pre-operative radiological examinations it appears that (describe relation between teeth and sinus membrane):
……
……
……
……

Further risks and clarifications:
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……

□ **D) UPPER-ANTERIOR-CENTRAL SECTORS**
The extraction of teeth in this sector may lead to:
- discomfort in aesthetic and phonation; displacement of adjacent teeth; bleeding; fracture or loss of contiguous elements, especially in the presence of previous pathologies affecting the supporting tissues of the teeth; occlusal disorders and/or of the TMJ (incisors have a role in guiding protruding movements of the jaw);
- bleeding (profusely in case of damage to major blood vessels in such area);
- temporary anaesthesia of the anterior portion of the hard palate due to severing of the relative nerve, especially in the removal of retro-incisal supernumerary teeth.

Further risks and details:
……
……
……
……

□ **3.2.4.) PARTICULAR HEALTH CONDITIONS OF THE PATIENT MAY INCREASE RISK OF:**

□ **A)** osteomyelitis of the maxilla – inflammatory process linked to bacterial infection that can lead to abscess or, worse, sepsis. Such condition is rare but most frequent in immune-depressed patients;
□ **B)** necrosis of the alveolus with difficulty in healing process in patients treated with anti-bone-reabsorption drugs (bisphosphonates/amino-bisphosphonates) and/or undergoing radiation therapy to the head or neck;
□ **C)** fracture of the jaw**.** Rare event, but most frequent in extractions of teeth located in posterior-lateral sectors of the jaw especially if the patient suffers from: osteoporosis, rickets, osteomalacia, acute or chronic osteitis, bone dysplasia, large cysts, tumours;
□ **D)** bleeding for prolonged time or even much after the end of the operation. Can manifest if the patient is under antiplatelet or blood thinning medication. Medical intervention might be requested.

Further risks and details:
.....
.....
.....

3.2.5.) I declare to have been fully verbally informed by the medical personnel whom have done the examination of the aforementioned risks; I further declare to have fully understood the implied risks thanks to the complete explanation provided by the doctors.
I am aware that risks persist despite the most scrupulous observance of the precautionary rules and in accordance with the best practice.
I am fully aware that the mentioned risks include the most common inconveniences related to extractive therapy; any further and more detailed information has been given to me by the examining medical personnel in relation to my specific case.
I am aware that post-extraction, in order to restore function and aesthetic, the use or prosthetics (mobile or fixed) may be needed.
I declare to understand the possibility to submit to new radiologic examination in order to verify the complete success of the therapy and to monitor the situation.
I am aware that the non-treatment of the diagnosed pathology can result in a worsening of said condition needing of more invasive treatments.
I further declare to have received detailed instructions regarding the post-operation maintenance, to have understood its meaning and recognise the risks possible if not done as suggested.

3.2.6.) The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after the evaluation of the following alternative therapies
.....
.....
.....

□ **3.2.7.)** I also authorize, as a result of the verbal colloquy with the medical staff, in consideration of the alternatives proposed and aware that without this specific authorization the patient should carry out further interventions under general anaesthesia (with the relative risks), to the extraction of other elements than those specified in paragraph 3.2.1. when, from inspection of the patient's oral cavity (subjected to the operations prescribed under conditions of general anaesthesia for the reasons marked in section 4.2) and from the completion of the necessary intraoperative radiographic investigations, it results that other teeth are affected, jointly or alternatively by:
A) carious lesions which impede a safe preservation of the dental element;
B) lesion of endodontic origin which damages the periapical tissue of the tooth (periodontal ligament, alveolar bone) and of which the non-treatment may result in an abscess with or without fistolization and possible extension to adjacent structures (sinus cavity, floor of the mouth or submental space in worst case scenario);
C) periodontal disease undermining the normal structural support of the teeth;
D) other (specify)
.....
.....
.....

The non-authorization referred to in paragraph 3.2.7. involves the need for a new intervention under general anaesthesia for the treatment of the diseases found during the allowed intervention.

Signature of the legal representative of the patient

X .....

4) ANAESTHESIA

□ **4.1.)** Dental practices require the use of drugs to anaesthetize the treated areas (local anaesthesia).

4.1.1.) In the upper maxilla, anaesthesia consists of injecting the anaesthetic in proximity of the structures to treat (local peripheral anaesthesia); when treatment involves larger areas or specifically elements in lateral-posterior sector of the jaw (3.5 to 3.8 and 4.5 to 4.8) the common practice is to inoculate the anaesthetic close to a nervous trunk (nerve block anaesthesia).

4.1.2.) Intrapulpal anaesthesia. Consists of the inoculation of anaesthetic directly in the dental pulp after breaching through the crown. This method may be necessary when the techniques used in paragraph 4.1.1 don't prove to be efficient. It may require the use of sedatives or of nitrous oxide through inhalation.

4.1.3.) Intrabony anaesthesia. Done by injecting anaesthetic directly inside primary spongiosa of the bone around the tooth. The technique may require a incision and use of a reamer in order to penetrate the bone.

4.1.4.) Intraligament anaesthesia. Consists of the injection of anaesthetic in the periodontal ligament. It's indicated in the inferior alveolar nerve block on patients with severe blood clotting diseases in order to reduce risks of haemorrhage or when other techniques prove inefficient. It brings substantial post-op pain.

4.1.5. In the present case, the indicated technique is the one reported in:
□ 4.1.1. □ 4.1.2. □ 4.1.3. □ 4.1.4.

4.1.6. RISKS AND CONTRAINDICATIONS TO LOCAL ANAESTHESIA

Anaesthesia is generally a safe medical practice. Nevertheless, in specific conditions (when the patient has an unknown previous pathology or omit to communicate a known pathology during the anamnestic survey) this treatment can lead to: Intoxication due to the anaesthetic and/or associated substances (overdose or normal dose in patients with metabolic deficiencies); allergic reactions to the drugs used (bronchospasm or edema of the larynx) up to anaphylactic shock; worsening of cardiac or circulatory conditions in patients at risk; increase of intraocular pressure; necrosis of tissues; hematoma; hepatic or aphthous manifestations post anaesthesia; neurological excitement; tremors; disorientation; dizziness; excessive sweating; arrhythmia; nausea and vomit. In sensitive patients urticaria and cutaneous rash can manifest.

□ **4.1.7.)** When the operation requires, like the present case, nerve block anaesthesia, the following risks are possible: A) paralysis of the facial nerve (rare, due to an injection done too posteriorly in respect to the spyx spine); B) paraesthesia due to lesion of the nervous trunk due to damage caused by the needle of due to prolonged compression; C) lockjaw (spastic muscle contraction impeding the normal opening of the mouth) derived by laceration, haematoma or direct injection in muscle fibres of the relative masticatory muscle.

4.1.8.) I declare to have been fully verbally informed by the medical personnel whom have done the examination of the aforementioned risks; I further declare to have fully understood the implied risks thanks to the complete explanation provided by the doctors. I am aware that risks persist despite the most scrupulous observance of the precautionary rules and in accordance with the best practice.
I am fully aware that the mentioned risks include the most common inconveniences related to anaesthetic techniques; any further and more detailed information has been given to me by the examining medical personnel in relation to my specific case and specific technique.
I am aware that during the anaesthesia, further anaesthetic techniques may be required in consequence of a fading effect of the utilized drugs, and I hereby authorize consent.
I further declare, under my responsibility, to have given all necessary information and to have answered truthfully to all questions asked by medical staff in order for them to choose the most appropriate anaesthetic technique (highest effectiveness, lowest chance of risks) for the present situation.

Signature of the legal representative of the patient

X ……

□ **4.2.)** The present case, in view of the specific clinical conditions, needs general anaesthesia to perform the required dental therapies.
In the present case, the need of general anaesthesia depends on: □ inability to cooperate due to conditions such as: autism, idiopathic mental retardation or due to precise pathologies or syndromes, cerebral palsy or psychiatric disorders; □ lack of efficacy/possibility of using local anaesthetics, due to acute infection, anatomical variants or allergies; □ immediate need for invasive therapies, of a surgical or multi-specialized nature; □ presence of high-risk systemic conditions, for which an intraoperative control of the vital parameters is indicated under general anaesthesia; □ other (specify)
……
……
……

For a description of the operation, risk prospect, contraindications and post-operative care linked to the general anaesthesia please refer to the documentation of consent given by the anaesthesiologist.

The selection of paragraph 4.2, even in presence of the underwriting at the bottom of the form, does not constitute consensus to the indicated therapies, when the anaesthetist documentation is absent.

5) RADIOGRAPHIC EXAMINATIONS

□ **5.1.)** The intraoral radiography is an image acquired in order to study the anatomy of a maximum of three teeth per image.

It is the diagnostic technique of choice for root canal therapies as it allows to accurately indicate the number, anatomy and the possible presence of lateral root canals whose lack of cleansing and subsequent sealing would compromise the entire treatment; during the intraoperative phase, it also reduces the risk of injury to anatomical structures close to the operative field, such as the dental roots or the mandibular canal.

□ **5.2.) Complete intra-oral examination** consists of executing numerous intraoral acquisitions in order to complete an image of both dental arches.

RISKS AND CONTRAINDICATIONS: Emission of minimal doses of ionizing radiation to which the patient is protected through he uses of shielding devices. No complications linked to the examination have been reported.

I declare to have been fully verbally informed by the medical personnel whom have done the examination of the aforementioned risks; I further declare to have fully understood the implied risks thanks to the complete explanation provided by the doctors.

I further declare, under my responsibility, to have given all necessary information and to have answered truthfully to all questions asked by medical staff.

I further declare that the patient is not in state of pregnancy and to have received from the medical staff a prospect of possible risks for the foetus.

I am aware that the lack of authorization to investigations indicated in chapter 5 of this form may not allow the execution of dental therapies and/or increase the risk of the intervention.

Signature of the legal representative of the patient

X ……

6) ATYPICAL OPERATIONS

Type of operation

……
……
……

Description of the operation

……
……
……

Risks and possible post-operative disorders

……
……
……

For the present case, the teeth involved are:

……

7) OTHER INFORMATION REQUESTED BY THE PATIENT

……
……
……
……

In case of failure to complete chapter 7 of this form, the legal representative of the patient declares that he has not exposed to the medical staff in charge further clarifications on the prescribed therapies and that he is therefore satisfied with the information received.

******

I, the undersigned ……,
in the quality indicated in the epigraph of this form,

DECLARE

- To have received complete information of the therapies prescribed and relative post-operative care;
- To have fully understood the aim and nature of the therapies prescribed and operations;
- To be aware of risks and complications that can derive from the operations and from the anaesthetic treatment;
- To have asked all relative questions in order to allow a full understanding of the prescribed therapies and operations;
- To have answered truthfully to all medical questions asked from the staff and to be aware of the possible risk that lying could cause to the patients' health;
- To be aware that the present module has a complementary role to the information verbally given by the staff "CUO of paediatric dentistry and odontostomatology of the University Hospital "Policlinico Umberto I";
- To be aware that for success of prescribed therapies is necessary patient and/or its legal representative collaboration;
- To be aware that further visits will be necessary in order to monitor the pathology treated and prevent complications and/or the onset of further pathologies;
- To have received precise instructions on oral hygiene techniques to use at home;
- That the form was completed in my presence and under my strict supervision;
- To have verified that the module is composed of exactly 10 (teen) pages and presents the partition indicated by the letter c) of the notes; and to have also verified its conformity to the computer document published on the institutional site of the dental clinic and displayed on the premises of the department[1];

I give, therefore, my consent to the execution of the operations indicated by the marked paragraphs of this form.
I give, moreover, the consent to the execution and saving of photos and videos for diagnostic, research and teaching purposes also consenting to their use in books and scientific journals.

Rome, date: ……/ ……/……

Signature of the legal representative of the patient

X ……

Doctors' signature

X ……

NOTES.
A) For the purposes of this form, with the use of expressions such as; therapies/intervention/operation/marked and/or selected paragraphs/refer to the placing of an X (or other symbols e.g. √) in appropriate boxes (□) which juxtapose chapters and paragraphs.
B) The selection and/or marking of the boxes implies that the consent refers to the therapies indicated in the relative paragraph. If the paragraph refers to therapies, risks, disorders, post-operative courses treated in other sections of the module, it is supposed these are understood by the patient's legal representative.
C) the present form is composed by: heading; epigraph (information regarding patient or legal representative); chapters 1) conservative treatment; 2) endodontic therapy; 3) oral surgery; 4) anaesthesia; 5) radiographic examination; 6) atypical therapies/details on concorded therapies; 7) other information as requested by the patient; paragraphs (subdivisions of chapters; they are identified with two Arabic numerals spaced by a point; the number that precedes the point indicates the chapter to which it belongs; subparagraphs; authorization to therapies).
D) Some chapters and/or paragraphs require an autonomous subscription. These do not replace the signature at the bottom of the form (which must always be present) but are intended to focus the attention of the patient's legal representative on the specific therapies and the related risks and/or contraindications. Failure to sign at the bottom of the chapters/paragraphs marked (where required) implies the lack of consent to the relative therapies.

Attachment B

DECLARATION OF RECEIVED INFORMATION AND CONSENT TO ORTHODONTIC THERAPIES

I, the undersigned ……..
(CF……..)
as □ parent □ legal tutor of .....
(CF……..)
already fully informed on prescribed therapies during the verbal interview with the medical staff of Paediatric Dentistry and Odontostomatology Complex Operative Unit, in full awareness, consent to the application of the operations indicated below:

FIRST VISIT CLINICAL EVALUATION

The clinical examination, cephalometric analysis and inspection of the study models highlight the presence of:

A. □ **cross-bite.** An inverted occlusion between upper and lower teeth. In the present case is: □ **anterior** (the upper incisors occlude posteriorly to the lower incisors) □ **posterior** (the upper-lateral-posterior elements occlude more inwards than the lower antagonists); □ **skeletal** (the cross-bite depends on a discordant growth between the maxilla and jaw bones); □ **dental** (the malocclusion depends solely on a misalignment of teeth); □ **unilateral**; □ **bilateral**;

B. □ **open bite** (incomplete closure between dental arches in occlusion). In the present case is: □ **anterior** (space remains between frontal sector teeth); □ **posterior** (space remains between posterior sector teeth);

C. □ **tongue interference** (during normal deglutition the tongue does not interfere with the frontal dental elements, in this case instead the tongue exerts a pressure towards frontal teeth determining an incomplete closure and vestibular inclination of the incisors).

D. □ **deep bite** (occlusion in which superior frontal teeth cover, excessively, the lower frontal teeth);

E. □ **malocclusion II class:** □ the jaw presents a slower growth or a stunted growth and therefore positions itself posteriorly in respect to the position of the upper maxilla; □ the upper maxilla has an increased growth or a faster growth and therefore positions itself too anteriorly in respect to the jaw;

F. □ **malocclusion III class**: □ the jaw has an excessive growth and positions itself too anteriorly in respect to the upper maxilla; □ the upper maxilla has a stunted or slower growth and positions itself too posteriorly in respect to the jaw. Both conditions can lead to a crown-to-crown occlusion or a condition in which the lower incisors occlude anteriorly to the upper incisors.

G. □ loss of useful space (condition in which the early loss of primary teeth determines the misalignment of erupted teeth in an attempt to fill the gaps left by the lost primary teeth);

H. □ **onychophagy** (habit to chew and eat the free margin of nails, can cause malocclusion and systemic problems);

I. □ **Lip interposition** (condition in which the lower lip interferes between the dental arches, it can cause a forward inclination of anterior teeth and incomplete closure);

J. □ **misalignment**;

other
……
……
……

The patients' clinical condition requires a customized treatment. For such requirement, we suggest to prescribe:

1) INTERCEPTIVE THERAPY WITH PRECONSTRUCTED DEVICES

The therapy is needed to correct any skeletal alterations which, if not treated in early stages, can worsen in time. Moreover, the correct eruption of teeth and correction of bad oral habits are stimulated.
Once the appropriate examinations have been carried out, the following is prescribed:

□ 1.1.) Therapy with "*Occlus-o-Guide*" devices
Occlus-o-Guide is a preconstructed device in soft and transparent material which allows the correct eruption of teeth and the alignment of them. The therapy aims to stimulate jaw growth and inhibit maxillary growth. For such aim the jaw is kept in a forward position with incisors occluding "crown-to-crown".
From the interceptive point of view, the device works as a muscle-regulator, correcting the posture of the tongue. The correct use, as prescribed by the medical staff, allows the re-education of the atypical deglutition and stimulation of a correct breathing pattern.

□ 1.2.) Therapy with "*Nite Guide*" devices
Nite Guide it's a preconstructed device in elastodontic material which guides the inferior permanent incisors during eruption in order to achieve correct occlusion. It's used generally on 5 to 7 years old patients and mainly during night-time. After the age of 7, therapy can continue with the use of Occlus-o-Guide devices.

□ 1.3.) Therapy with "*Habit corrector*" devices
Habit corrector is a preconstructed device used in paediatric patients in order to correct open-bites caused by bad oral habits. Therapy with Habit corrector further allows a greater effectiveness of future orthodontic treatments since it favours a correct alignment and eruption of teeth. It's characterized by two elements for lingual re-education: a rough surface and two spurs restricting access to the lower half of the oral cavity.

□ 1.4.) Therapy with the following elastodontic devices
……
……
……

Description of the device prescribed and therapy:
……
……
……
……

1.5.) Things patient and its legal representative have to know

A. Therapy with devices in elastodontic material is minimally invasive. The effectiveness of the treatment is conditioned by the biological response of the patient; therefore, the attaining of results is purely theoretic and is only of example of the results wanted by the orthodontic therapy. By giving consensus to the therapy prescribed the patient, or its legal representative, declare to be aware of this aspect of the therapy.

B. Being all devices removable, the effectiveness of the therapy largely depends on the collaboration of the patients to the prescribed use of said devices. In other words, if the patient accurately follows the prescription, the more favourable the results. The legal representative of the patient declares to be aware of this aspect and will encourage the correct use.

C. The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after evaluation of the following possible alternative therapies:
……
……
……
……

D. The legal representative of the patients declares the consensus has been given after having considered the risks and contraindications given by the medical personnel and after having read and fully understood chapter 6 of the present module.

Sign of the patients' legal representative

X ……

□ 2) PALATAL EXPANSION THERAPY

The palate expansion is an orthodontic therapy finalized to a correct occlusion in patients with a posterior cross-bite. In order to reach this objective, specific orthodontic devices are to be used.
The therapeutic planning will therefore take into account age of the patient, severity and type of the malocclusion.
Given the appropriate examinations have been carried out, the following is prescribed:

□ 2.1.) Palatal expansion therapy with "*hyrax*" device
Hyrax devices are characterized by an expansion screw positioned at the centre of the palate and fixed to the upper morals by metal arms conjoined to the metallic molar bands. The cementing of such bands is achieved through the use of vetro-ionomeric cements with high release of fluoride in order to prevent carious lesions.
To maximize the transmission of the expansion force, the metal bands can also be arranged on several dental elements.
The therapy requires that the screw on the palate performs two rounds a day (one in the morning and one in the evening).

□ 2.2.) Palatal expansion therapy with "*McNamara*" device

McNamara is indicated for patients in mixed dentition. The device anchors itself on at least two permanent teeth (molars) and four primary teeth. In some cases, anchorage is required also on primary canines using resin.

Therapy with McNamara expansion device avoids further opening of open-bites since it causes intrusion of posterior teeth.

The cementing of such device is achieved through the use of vetro-ionomeric cements with high release of fluoride in order to prevent carious lesions.

□ 2.3.) Palate expansion therapy with following device:

……
……

Description of device used and therapy:

……
……

2.4.) RISKS AND CONTRAINDICATIONS TO PRESCRIBED THERAPIES

With each activation of the device some tension can be felt on teeth or nose. This feeling will be present for a few minutes along with possible excessive salivation, difficulty in speaking and swallowing: it's all normal and will pass in a few hours.

The appearance of ulcers on the palatal mucosa must be reported to the medical staff.

During palatal expansion one can observe a central diastema (presence of space between the central incisive teeth) which will require no assistance as it will correct itself after the activation phase. It is a clear sign of the function of the device.

2.5.) Things patient and its legal representative have to know

A. The achievement of the goals of the therapy depends strictly on the age of the patient. The bones of the palate tend to weld around 12/13 years in girls and 13/14 years in boys; therefore, the most satisfactory results are obtained by intercepting malocclusion early in age.
It must also be considered that the response of biological tissues to the mechanical stress applied by the device varies from subject to subject; therefore, the eventual result of the therapy is subject to individual variation since it is not possible to predict specifically the response of the subject's tissues.

B. When the device is applied, the instructions for activating it are provided to the patient's legal representative. Following these instructions is essential for the successful outcome of the therapy. By consenting to the treatment, the legal representative of the patient declares to have understood the importance of his collaboration for the success of the treatment and states to diligently respect the indications provided for this purpose by the medical staff in charge.

C. The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after evaluation of the following possible alternative therapies:

……
……

D. The legal representative of the patient states that the consent was formed only after having considered the risks and contraindications communicated by the medical staff and, in any case, after having read and fully understood paragraph 2.3 of this chapter and chapter 6 of the present form.

Sign of the legal representative

X ……

3) SPACE MANAGMENT THERAPY; INTERCEPTIVE THERAPY FOR II CLASS MALOCCLUSION

In consideration of the diagnosis formulated on page 1, it is prescribed:

3.1.) Therapy for the preservation or recovery of arch space. Aim: avoiding loss of arch space due to premature exfoliation of primary teeth and subsequent movement of adjacent teeth.

3.2.) Interceptive therapy for class II malocclusions. Aim: to bring the jaw forward in order to correct abnormalities of development of the jaws.

For the achievement of the described purposes the following devices must be applied:

A) *Schwartz plaque*. It's a palatal device constituted by a resin plate, prosthetic hooks applied on the molars and a metallic arch passing in front of anterior upper incisors. Inside the resin plate a set of screws is present, allowing for an activation leading to a transversal or longitudinal expansion. Single springs can be applied in order to act on single teeth.

B) *Band with loop*. It's a fixed unilateral device indicated in situations where preservation of posterior arch space is crucial. It consists of a metallic band placed on a molar with a metallic arm resting on the first anterior erupted tooth.
C) *Lingual arch*. It's a fixed device consisting of two metallic bands applied on the primary molars and an orthodontic arch adjacent to the lingual surface of the dental elements. It prevents the molars from moving anteriorly and occupying the eruption space of permanent teeth along with avoiding misalignments.
D) *Palatal arch*. It's a fixed device consisting of metallic bands applied onto the molars and a curved orthodontic wire connecting the bands and passing in contact with the palate. It avoids the movement of molars in spaces left behind by premature loss or exfoliation of primary teeth.
E) *Lip bumper*. It's a mobile functional device consisting of two metallic bands cemented on the first permanent molars, a metal arch passing on the vestibular face of inferior-anterior teeth and a resin shield in contact with the interior of the lower lip. In the present case it is applied because of:
E.1. realigning the first permanent molars which are inclined due to lack of space; **E.2.** preserve space left by premature loss or exfoliation of primary teeth; **E.3.** recover space lost during primary teeth exfoliation, by rebalancing muscular forces of the lip and cheeks; **E.**4 stimulate the mandibular growth by exploiting the backward thrust of the lower lip muscles to counteract the stretching induced by the resinous shield; **E.5. other reasons/details**
……
……
……

F) "*Frankel II*" device. It's a functional orthodontic device which works by keeping the jaw in a forward position in order to stimulate its growth; at the same time decreases the distance between the teeth of the upper and lower arch. It has a metal frame that attaches to the upper molars and to which resinous shields are connected, which are positioned between the patient's teeth and cheeks.
G) "*Twin Block*" device. It's a functional orthodontic device consisting of an inferior device cemented to the molars via metallic bands and an upper mobile device. Both devices consist of a metal structure to which resin plates are applied. The therapy aims to stimulate mandibular growth by reducing the longitudinal distance between the arches.

H) Other device
……
……
……

Description of device and relating therapy:
……
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Additional details on prescribed therapy:
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3.3.) Things patient and its legal representative have to know

A. The space preservation therapies indicated in paragraph 3.1 only aim to preserve or recover the space for the eruption of the final dental elements. The achievement of this goal does not necessarily entail the correct alignment of the teeth; the legal representative of the patient declares himself therefore aware of the possibility of further orthodontic treatments to obtain a correct occlusion (both functional and aesthetic).
B. The duration of treatment depends on the physiological response of the patient and cannot be accurately predetermined. The indication of the maximum duration of orthodontic therapy is therefore merely indicative/theoretical and is based on scientific experience and clinical evidence; the legal representative of the patient, consenting to the care of the case, declares to have become aware of this aspect.
C. The legal representative of the patient declares to be aware that further orthodontic therapies may be required in order to consolidate the results achieved with the prescribed therapies.
D. All prescribed therapies, particularly those employing mobile devices, require maximum patient collaboration to achieve orthodontic results. The legal representative of the patient declares to be aware of this aspect and undertakes to comply with the instructions for the home management of the device communicated by the medical personnel in charge.
E. The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after evaluation of the following possible alternative therapies:
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……
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F. The legal representative of the patient states that consent was formed only after having considered the risks and contraindications communicated by the medical staff and, in any case, after having read fully understood chapter 4 of this form.

Signature of the legal representative of the patient

X .....

4) THERAPY FOR III CLASS MALOCCULSION WITH DELAIRE MASK

The therapy is finalized to the harmonious development of the jaws in patients who present an excessive growth of the jaw or a stunted growth of the maxilla; this condition can lead to a "crown-to-crown" occlusion, or worse, anterior cross-bite (superior front teeth behind the inferior ones).
The correction of this III class malocclusion can be obtained by the combined use of an intraoral device and an extraoral device.

Intraoral anchorage is practiced by applying metal bands on the posterior teeth of the maxilla or by fixing metal arches on the palate. Externally, the mask consists instead of a forehead rest and a chin rest. Both rests are linked by a metal chassis which includes two hooks for the elastic bands which are then hooked up on the intraoral device.

4.1.) Things patient and its legal representative have to know

A. The response of biological tissues to the mechanical stress of the apparatus varies from subject to subject; therefore, the eventual result of the therapy is subject to individual variation since it is not possible to predict specifically the response of the subject's tissues. The eventual indication of definitive outcomes is purely functional to the therapy explanation and does not constitute a definitive result.

B. The stability of the therapy results can be compromised by the general growth of the patient with non-predictable outcomes at the time of treatment prescription. Therefore, further orthodontic therapies may be required and, in the most severe cases, surgical interventions to consolidate and/or restore the correct occlusion. To this aim, a follow up plan could be necessary, which can continue up to 18 years of age, and needs to be followed in order to intercept any relapse.

C. Therapy with "Delaire mask" requires a strict collaboration with the patient, therefore following the indications of the medical staff is crucial to success. The patient must be careful in following all appointments and correct maintenance of devices. Success is also dependent on dental hygiene both at home, or if needed, professionally. In order to verify the ongoing results during therapy radiographic exams may be necessary.

D. Therapy generally requires the application of the mask for 18 months. This data is a mean value based on the diligent use of the device, on compliance with the prescriptions of the orthodontist and the established check-ups. The duration of therapy is also affected by tissue response to orthodontic forces with considerable patient-to-patient variability.
The eventual indication of prefixed times of the therapies has therefore an indicative/theoretical character.

E. Use of the device may cause reddening in correspondence with the resting points of the mask (chin and forehead). These symptoms must be promptly communicated to the orthodontist who will be able to evaluate the possibility to interrupt the treatment.

F. The legal representative declares that he has received the information necessary for managing the device and being able to correctly practice the maneuvers for inserting and removing the mask. The orthodontist and the dental clinic disclaim all responsibility for the improper use of the mask.

G. The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after evaluation of the following possible alternative therapies:

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H. The legal representative of the patient states that consent was formed only after having considered the risks and contraindications communicated by the medical staff and, in any case, after reading chapter 6 of this form.

By consenting to therapies, the legal representative declares to having read and fully understood, all the points previously presented in the module.

Sign of the legal representative

X .....

5) MULTIBRACKET THERAPY

The therapy consists in the application of orthodontic brackets on the dental elements through the use of composite materials. The brackets are then connected to each other with metal wires that have the task of transferring orthodontic forces to the dental elements.
The aim of the therapy is to obtain a correct occlusion by realigning the dental elements. The realignment is also finalized to allow a more complete and correct oral hygiene.

5.1.) Things patient and its legal representative have to know

A. The results achieved with multibracket therapy are generally satisfactory. Nevertheless, the personal/biological factor has a significant influence on the outcomes of the treatment; the response of the tissues to the application of orthodontic forces is variable from subject to subject and depends on numerous factors (age, positioning of the teeth, presence of spaces to allow dental movements). The eventual prospect of a result, at the moment of the acquisition of the consent to the treatment, or during the necessary visits, has the only purpose to illustrate the aim which the therapy leads to and not to guarantee the final result; the legal representative of the patient, consenting to the care of the case, declares to be aware of this aspect.

B. The considerations made in the previous point A are valid, even more so, to duration of the therapy. Any indication of a term of care is indicative/theoretical considering the subjective variability of biological tissues to the application of orthodontic forces; the legal representative of the patient, consenting to the treatment, declares to be aware of this aspect.

C. Patient collaboration is essential for a successful therapy. The success of the treatment depends on: the management of the device according to the methods communicated; the strict observance of the check-ups; the timely communication of any changes in the structure or mechanics of the orthodontic device. Particular attention must be paid to the practices of oral hygiene at home and, when necessary, professional hygiene must be done. The legal representative, and the patient, both agree to provide the collaboration required in the knowledge that in the absence of full collaboration, the therapy may not achieve the expected success.

D. The response of the tissues to the therapies may determine the need for changes to the initial treatment plan established at the time of the given consent; the legal representative of the patient, giving consent to the treatment, declares himself aware of this eventuality.

E. The legal representative of the patient states that consent was formed only after having considered the risks and contraindications communicated by the medical staff and, in any case, after having read and fully understood chapter 6 of this form.

F. The removal procedure of the orthodontic device can determine the detachment of previous dental reconstructions, making necessary a new conservative therapy.

G. The legal representative of the patient further declares that the consensus to the prescribed therapies has been taken in accordance with the medical staff after evaluation of the following possible alternative therapies:

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Sign of the legal representative

X……

6) RISKS AND CONTRAINDICATIONS OF THE PRESCRIBED THERAPIES

A. Pain. Following the application of an orthodontic force, the patient may experience a painful sensation of various magnitudes after about 2-3 hours which may last approximately 48/72 hours.

B. Detachment of a band or a bracket (for therapies in chapters 2, 3 and 5). Detachment or fracture of equipment must be communicated to avoid possible injuries to the teeth, gums and cheeks; these events can also modify the action of the device causing delays or failures in the therapies.

C. Caries and inflammation of the gums. Orthodontic appliances do not in themselves cause tooth decay. However, the presence of stationary equipment can make brushing more difficult and promote the build-up of bacterial plaque. These conditions may increase the risk of developing caries and/or inflammatory processes in the gingival tissues (swelling, redness and bleeding of the gums). Sometimes the fixed device can also injure or compress the gingiva also causing injuries on the inside of the cheek. In some cases, the therapy can compromise the gingival tissue and require the help of specific therapies by another specialist (hygienist, periodontist, surgeon) or force a temporary suspension or early interruption of orthodontic treatment.

D. **Root resorption**. Consists in the reduction of root height with possible consequences on the overall tooth stability. The risk is generally low, however some pathological conditions can increase the probability and entity of the resorption.
E. **Loss of tooth vitality.** A past trauma, carious lesion, could have caused damage to the dental pulp. The endodontic lesion could be diagnosed during orthodontic therapy and therefore require specialist treatment (root canal therapy) in order to preserve the tooth.
F. **Dental ankylosis.** Consists of the fusion between bone and tooth root and it impedes all movements of the single tooth involved. It can manifest on all teeth, but it usually displays on traumatized teeth or impacted teeth.
G. **Relapsing misalignment.** Tendency to misalignment after removal of the device is normal. This tendency is much greater if bad oral habits persist (primary deglutition, oral respiration), after dental extraction, or after inflammation of the support tissues. The relapse can be avoided with a teeth-restraining-device. The restraint phase is important just as much as the active phase and should be kept for as long as possible.
H. Further risks:

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7) CONSEQUENCES OF THE LACK OF TREATMENT

The legal representative of the patient declares to have been informed that in the absence of orthodontic treatment could determine: A) aggravation of existing malocclusion or development of malocclusion; B) disorders of the masticatory function and alterations of the temporomandibular joint; C) diseases of the oral mucosa and of the dental elements (realignment allows better oral hygiene); others……
……
……

8) OTHER INFORMATION REQUESTED BY THE PATIENT

In the event of failure to complete Chapter 8 of this form, the legal representative of the patient declares that he has not asked the medical staff further clarifications on the prescribed therapies and that he is therefore satisfied with the information received.

……
……

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I, the undersigned ....., in the quality indicated at the top of this form,

DECLARE

- To have received complete information on the prescribed therapies and to have fully understood their purpose and nature;
- To be aware of the risks and complications of the prescribed therapies and that the relative citation has the only purpose of representing the most recurrent inconveniences in orthodontic practice. More detailed information was given to me by the medical staff, focusing on the specificity of my case;
- To have understood the significance of the risks thanks to the explanation provided by the medical staff and that these remain despite the most scrupulous observance of the precautionary rules and in accordance with the best practice.
- To have requested all the necessary information in order to consciously form consent to the prescribed, and agreed, therapies;
- To be aware that the successful outcome of orthodontic treatment requires the strict collaboration of the patient and therefore commit myself to comply with the indications provided by the medical staff;
- To have received the instructions for the home management of the orthodontic device and to fully understand its meaning and function;
- To have been informed of the possibility that the therapy can be interrupted, or suspended, in case of patient non-cooperation;
- To respect the agreed appointments for the check-ups and to be aware that their non-compliance can lead to failure or an incongruous outcome of the therapy;
- To have been informed that a restraining phase may be required after the completion of the prescribed therapy, even assisted by the application of new orthodontic devices, in order to preserve the results gained;
- To be aware that the duration of orthodontic treatment is influenced by the response of biological tissues to therapy. The variability of this factor does not allow to establish a certain time of care. I am aware, therefore, that the eventual indication of a term for the duration of the therapies is merely indicative;

- To be aware that the outcome of orthodontic treatment also depends on the response of biological tissues to the therapies and that this factor is variable from subject to subject. I am aware, therefore, that any prospect of a result has the only purpose of indicating the results of the therapy and not its effective achievement;
- To be aware that further radiological investigations may be necessary to verify the course of therapy (with related risks);
- To be aware that the lack of consent to the prescribed treatments may lead to the evolution or aggravation of the condition diagnosed and the possibility that the delay in treatment may not allow the achievement of optimal results;
- That the consent to the therapies was formed during colloquy with the medical staff and after examining the prospect of therapeutic alternatives;
- To be aware that this form has the mere function to complete what has already been said orally during the visit;
- That the form was completed in my presence and under my strict supervision;
- To have verified that the form delivered consists of pages 8 (eight) and presents the subdivision indicated in letter c) of the notes; to have also verified that it complies with the IT document published on the institutional site of the dental clinic and displayed on the premises of the department;
- To have carefully read the notes at the bottom of the form;[1]

I, therefore, give my consent to the prescribed and agreed interventions indicated by the marked paragraphs of this form.

In addition, I consent to the execution and conservation of photos and videos for diagnostic, research and teaching purposes and I also consent to their use in books and scientific journals.

Rome, date ……/ ……/……

Signature of the legal representative of the patient

X ……

Doctors' signature

X ……

[1] NOTES.
A) For the purposes of this form, with the use of expressions such as: therapies/intervention/operation/marked and/or selected paragraphs/chapter we refer to the placing of an X (or other symbols e.g. √) in appropriate boxes (□) which juxtapose chapters and paragraphs.
B) The selection and/or marking of the boxes implies that the consent refers to the therapies indicated in the relative paragraph/chapter. If the paragraph/chapter refers to therapies, risks, disorders, post-operative courses treated in other sections of the module, it is supposed these are understood by the patient's legal representative.
C) The present form is composed by: heading; epigraph (information regarding patient or legal representative); chapters 1) interceptive therapy with preconstructed devices; 2) palatal expansion therapy; 3) space managemen therapy; interceptive therapy for II class malocclusion;t; 4) therapy for III class malocclusion with Delaire mask; 5) multibracket therapy; 6) risks and contraindications of the prescribed therapies; 7) consequences of the lack of treatment; 8) Other information requested by the patient; paragraphs (subdivisions of chapters); they are identified with two Arabic numerals spaced by a point; the number that precedes the point indicates the chapter to which it belongs; subparagraphs; authorization to therapies.
D) Some chapters and/or paragraphs require an autonomous subscription. These do not replace the signature at the bottom of the form (which must always be present) but are intended to focus the attention of the patient's legal representative on the specific therapies and the related risks and/or contraindications. Failure to sign at the bottom of the chapters/paragraphs marked (where required) implies the lack of consent to the relative therapies.