

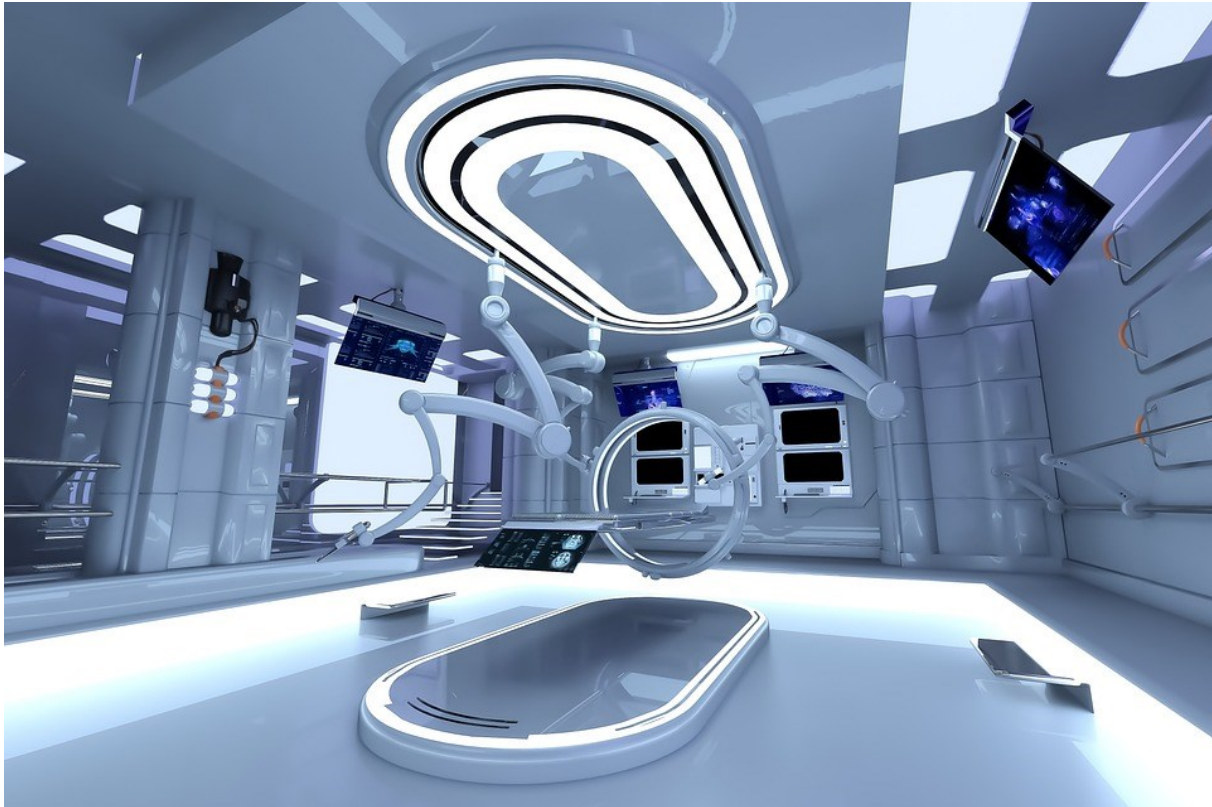
# “Can I protect my innovations for surgery? I heard surgery is excluded from patentability!”

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Yes, inventors can obtain a patent for innovations also in the field of surgery. After all, patents exist to stimulate innovation, and society welcomes innovation in the field of surgery.



However, the European Patent Convention (EPC) defines indeed an exception in Art. 53(c). Among other things, patents shall not be granted in respect of methods for treatment of the human or animal body by surgery. This exception exists in order to protect patients: no surgeon should be prevented from performing surgery because of intellectual property rights.

## Avoiding the exception

The exception has an effect on patent practise. The European Patent Office (EPO) does not grant a patent for a method if the patent’s scope of protection---the intellectual property defined by the *claims* of the patent---comprises a step of surgical nature practiced on a human or animal body. That is why drafting a European patent application requires care when surgery is involved, because the patent should be drafted so that surgical steps are clearly not part of the claims. Determining whether or not a claim comprises a step of surgical nature is not an easy task, because that hinges on what is considered a step of surgical nature. Dustin Vink provides more details in this regard [in his article on methods of treatment by surgery](#).

### Avoiding the exception for medical devices

The safest option for avoiding the exception may be to direct claims to a medical device instead of a method, because only method claims fall under the exception of Art. 53(c) EPC, but not device claims. For example, new medical instruments suitable for performing surgery (e.g., cutters, catheters) or for imaging a body (e.g., MRI or X-ray machines) can be patented.

### Avoiding the exception for algorithms

What if the invention is not about a new medical device, but is about a new method or a new algorithm assisting surgeons? Can such a new algorithm be patented?

The answer is a clear-cut “yes, but”. Yes, new algorithms assisting surgeons can also be patented. But, inventors and patent attorneys need to pay extra attention when drafting the patent in order to avoid the exception of Art. 53(c) EPC. Let us have a look at an example.

In the case T 2136/19, the patent in question related to a medical-data processing method suitable for assisting a surgeon in the positioning of a first medical structure relative to a second medical structure; for example, the positioning of a medical implant relative to a bony structure of a patient. The invention is phrased as a computer-implemented method that can be executed by a processor of a computer.

According to the patent application, the processor compares landmarks acquired in projection images (e.g., pre-operative x-ray images) with landmarks acquired directly on the patient’s anatomy (e.g., by a surgeon palpating the patient’s anatomy). The result of the comparison is shown to a surgeon as “correspondence information”, which enables the surgeon to verify the correct position of the medical structures relative to each other.

According to the Board deciding on this case, there was a potential problem to be solved: how can the EPO ensure that the claims of the patent do not comprise a step of surgical nature? The Board came to the following conclusion.

- Initially, the claimed method step for the landmarks acquired directly on the patient’s anatomy was worded as **“acquiring, by the computer, three-dimensional position data [...] in three-dimensional anatomical space”**.



The Board opined that this wording, in the light of the patent description, may be interpreted as encompassing a surgical step of obtaining the 3D position data by the surgeon palpating the patient's anatomy; for example, by the surgeon using a pointer in order to determine points on the bony anatomy of a patient.

- The Applicant submitted a new claim with the amended wording “***receiving, at the processor, three-dimensional position data [...] in three-dimensional anatomical space***”. The Board opined that this amended wording successfully avoids the exception: the step of acquiring the position data itself was no longer part of the claimed method and the surgical step was not encompassed, because there was no longer a functional link between the claimed method and any effect of a surgical nature.

So, in this case, the patent was drafted in a way that allowed the Applicant to avoid the exception of Art. 53(c) EPC. In the end, the claimed method was considered to be about assisting a surgeon by a purely “passive” data processing method that can be carried out exclusively in a computer without causing any effect in the patient's body as a result and not encompassing palpating the patient's anatomy or positioning of the medical structures.



### Take away

In principle, new algorithms for assisting surgeons can be patented. But whether or not a patent's claim defining the scope of protection for the new algorithm actually encompasses a step of surgical nature can only be determined on a case-by-case analysis. The example discussed above shows that the exception can sometimes be avoided by a change of wording of the claims.

### Any questions?

If you have any questions regarding IP protection of medical devices, do not hesitate to contact us via [Healthcare | NLO](#).

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