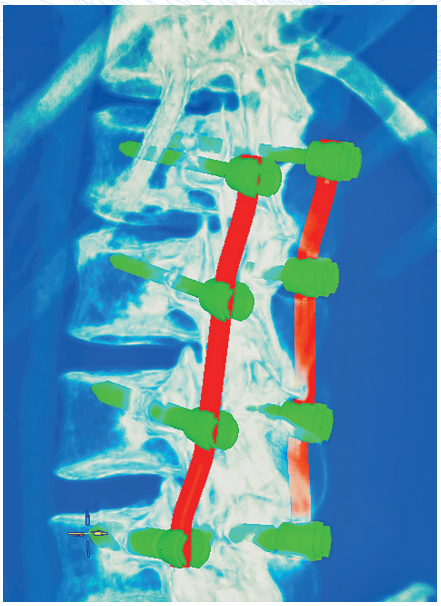
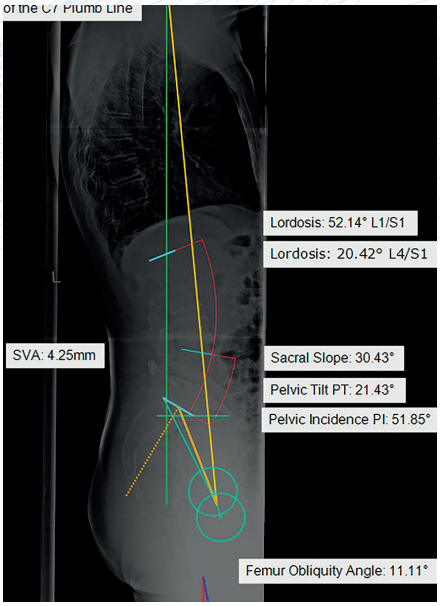
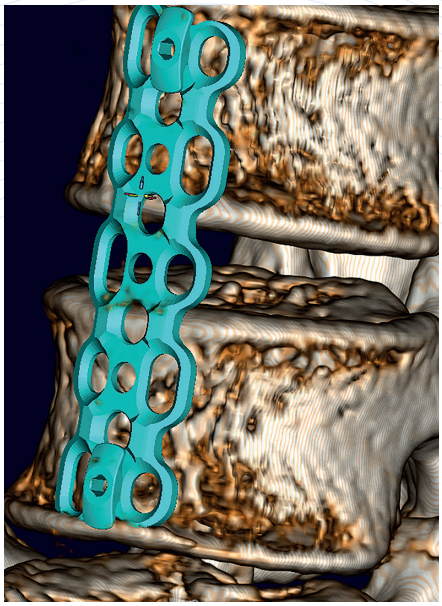
3D Spine

Sagittal Balance
Automatic Segmentation
Spondylodesis
Osteotomy
Implants

EU-MDR
Medical Device Regulation







mediCAD®

Software
Bundesverband IT-Mittelstand
Made in Germany

100%
Service
Qualität
Zukunft

www.mediCAD.eu

Greetings,

As quality consciousness continues to rise and well informed patients demand more and more from clinics and medical practices, we are committed to helping you meet these demands by offering the highest quality, most advanced products in professional, digital preparation for surgery.

Not only does **mediCAD® 3D Spine** provide quality assurance to your patients, it also saves time that you previously spent during actual surgery. In other words, this gives you significantly more time for consulting with your patient and preparing for surgery.

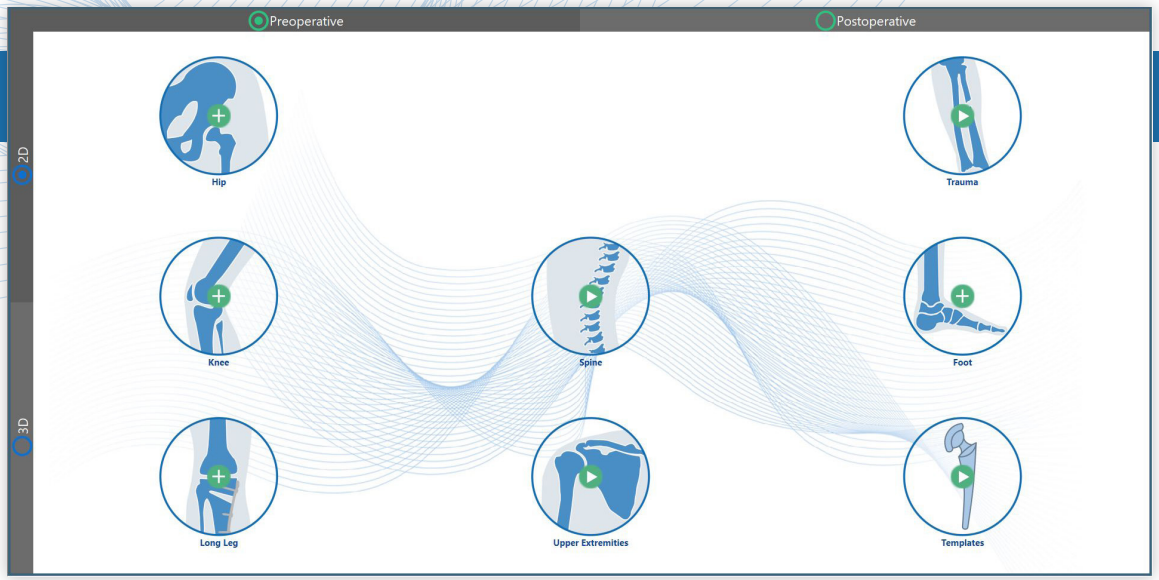
Scientific tasks should be simpler, faster, systematically supported and substantiated by up-to-date images that do not take a lot of time to prepare. Everyday consultations in your clinic should be more accessible and transparent and should offer easy-to-understand quality improvements and assurances.

Take a look at our user reviews. We are confident that you will be impressed by our carefully considered product concept and easy operation. You benefit from an implant database that is updated on a monthly basis and represents the very latest digital product catalog in the field of implant care.

Arrange a free and non-binding demonstration of our system – we're sure you'll be convinced.

We look forward to hearing from you soon.

With kind regards
mediCAD Hectec GmbH



mediCAD® is a combined package of modules, intended for use by trained medical specialists. It allows these specialists to assess bone and joint deformities, and plan implants for joint replacement and osteotomies based on 2D and 3D X-ray images.

The system was developed in collaboration with doctors for doctors, this means for you and your patients:

- World's first and most used planning program on the market
- Free interface to PACS via the **mediCAD®** Query Client
- Over 20,000 clinical users worldwide
- All known planning methods are taken into account
- A modular design with powerful add-on modules
- Easy and intuitive operation
- Immediate access to 23 languages
- All processes are documented in compliance with the law
- Time savings of up to 90% over conventional planning
- Access to more than 130 international implant manufacturers with more than 500.000 templates
- **mediCAD®** is continuously being developed with doctors for doctors
- Customized and special functions and modules are constantly being developed and made available
- **mediCAD®** has been successfully used in the medical industry for more than 20 years
- In international markets, **mediCAD®** is also sold under the name IMPAX Orthopaedic Tools (through AGFA Healthcare)
- **mediCAD®** is certified in accordance to 93/42/EWG und EN ISO 13485 and approved as a medical product
- MDSAP certified 512917MDSAP16 (AUS, BRA, CND, USA)
- 510(k) approval for mediCAD was granted by the FDA (K170702)
- **mediCAD®** is licensed for use as a medical device in the Russian Federation. Certificate, 2017/6580 dated 12/15/2017. Unique registry entry number 24304
- **mediCAD®** is licensed in Japan (JMDN CODE 70030012)

Features / Table of Contents

mediCAD® 3D Spine introduces you to entirely new possibilities for assessing, planning and measuring the anatomy of the spine and thus achieving an optimal and revision-safe surgery preparation.

The new modern and intuitive user interface takes you directly where you want to go and is conveniently paired with the existing connection to the PAC system in your clinic! These are just two of the many reasons that make **mediCAD® 3D Spine** an indispensable tool for your day-to-day work.

mediCAD® 3D Spine was developed in close collaboration with renowned spinal surgeons.

The core mission of our company is constant development and improvement.

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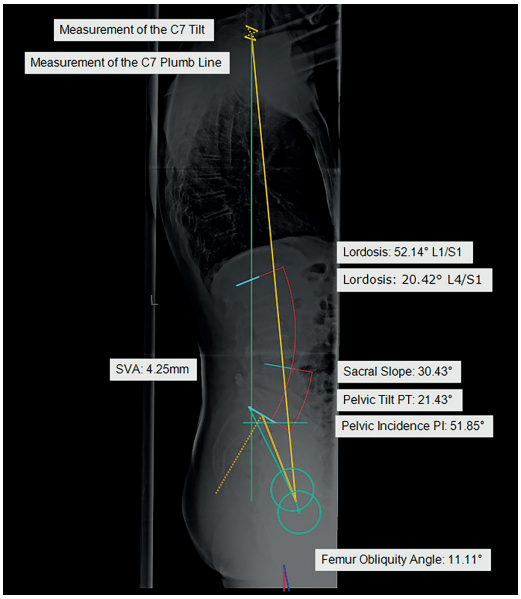
Sagittal Balance

Sagittal balance measurements can be executed in a single operation in **mediCAD® 3D Spine** using a function that intuitively guides the user. By setting just a few required reference points, all values are automatically calculated, plotted, and measured. As with automated measuring, the results are documented in a structured list and, when applicable, evaluated against normal ranges.

The following important values in spine surgery can be measured using this function:

- Sacral Slope SS
- Pelvic Tilt PT
- Pelvic Incidence PI
- Femur Obliquity Angle FOA
- Lordosis L1/S1 – L4/S1
- Pelvic Angulation PA
- Pelvisacral Angle PSA
- Pelvic Lordosis Angle PLA
- C7 Tilt
- C7 Plumb Line
- Sagittal Vertical Axis SVA



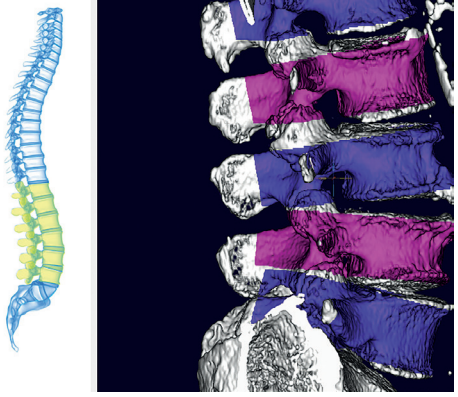
With just a few clicks, **mediCAD® 3D Spine** provides you with all the important data you need for further planning.

Segmentation / Measurements

mediCAD® 3D Spine allows you to perform both traditional, manual measurements and fully-automated dimensioning.

Automatic segmentation

When you load CT datasets, **mediCAD® 3D** automatically segments the 3D model.
Your image is precisely analyzed and compared with the dataset stored in the software, so based on this, all of the vertebrae and discs present in the image can be recognized and precisely categorized.
With the aid of a diagram of the spine, the vertebrae detected are depicted schematically and can then be adjusted or corrected manually if required.



Automatic segmentation helps you in the long term for later planning. It enables automatic measurements, automatic insertion and the placing of pedicle screws or cages in the correct vertebra and spondylodesis.

Automated measurements

mediCAD® 3D Spine automatically segments your CT images. A wide range of traditional measurements can then be carried out and recorded automatically:

- Scoliosis using Cobb's method
- Scoliosis using Ferguson's method
- Interpedicular distance
- Lordosis
- Pedicle depth
- Kyphosis
- Intervertebral disc height
- Intervertebral disc angle
- Spondylolisthesis
- Pedicle diameter

The results of the measurements are both displayed directly on the 3D model and recorded in a structured list of results. Where possible, an analysis based on the normal ranges is performed and positive or negative deviations are highlighted with a corresponding color.

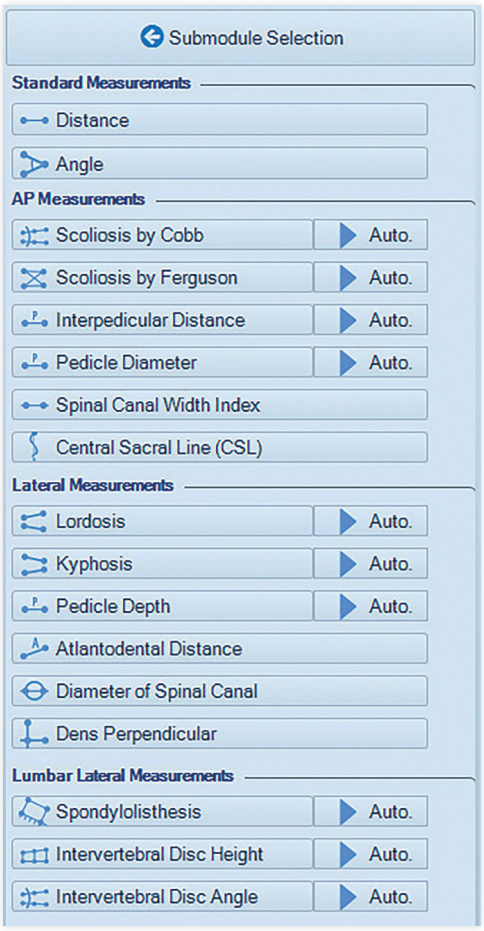
Segmentation / Measurements

Measurements performed manually

In addition to the automated measurements, all conventional measurements can still be performed manually.

mediCAD® 3D Spine has the option to perform the following measurements, simply and comfortable.

- Distance measurement
- Angle measurement
- Scoliosis using Cobb's method
- Scoliosis using Ferguson's method
- Interpedicular distance
- Pedicle diameter
- Spinal canal width index
- CSL (Central Sacral Line)
- Lordosis
- Kyphosis
- Pedicle depth
- Atlantodental interval
- Dens perpendicular
- Intervertebral disc height
- Intervertebral disc angle
- Spondylolisthesis

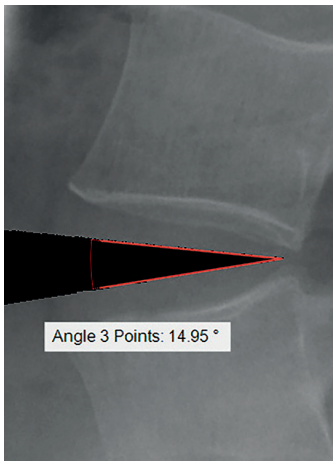


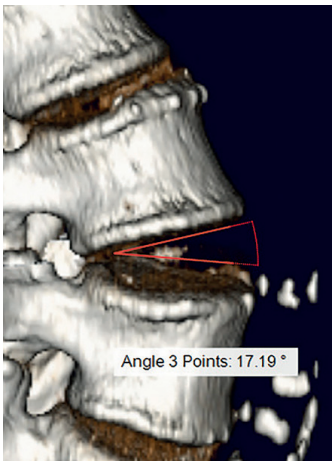
Deformity correction

Many functions in **mediCAD® 3D Spine** make it simpler for you to detect and correct spinal deformities.

Osteotomy

By specifying individual cuts or cut areas, you can perform one or more osteotomies and the resected areas can be moved or rotated as required. All measurements are automatically adjusted to reflect the new situation after performing the correction. This technique allows you to simulate and review various situations to find the best result for the patient.





The effects of each action on the sagittal profile of the patient can be monitored and depicted in real time. If specified, you can also perform an automatic alignment based on previously measured parameters once an osteotomy is completed.
In addition, **mediCAD® 3D Spine** can optionally suggest the optimal resection angle. This action facilitates automatic restoration of a harmonic spine profile for your patient.

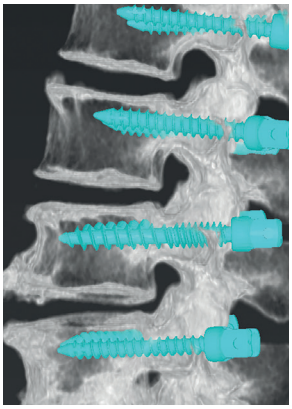
Screws / Implants / Cages

What screw length is required?
What is the ideal entry angle?
How deep should or can the screw be inserted?
How long is the required rod and which way should it be curved?
And which implant is best suited to a specific spine situation?

These questions and many more are answered by the convenient capabilities of **mediCAD® 3D Spine.**

Pedicle screws

The screw tool allows you to select from a variety of screw types and lengths. On a segmented 3D model, you also select the target vertebra and the screw side. The pedicle screw is automatically plotted in a standard position on the 3D model and you can adjust, rotate, shift, insert or switch to a different screw type or length entirely.



Implants

mediCAD® 3D Spine allows you to conveniently select the individual implant components in the implant tool and to place them in the 3D model. In addition to this, the implants can be adjusted, rotated, moved or changed to another implant type as a group or individually.

The implant tool allows you to select from a range of different spine implants, such as cages, plates, vertebral replacements or disc prostheses.
While doing so, you can use the implant tool to filter the implants based on manufacturer, type, material and size or simply list only your personal favorites or those most used in your clinic.

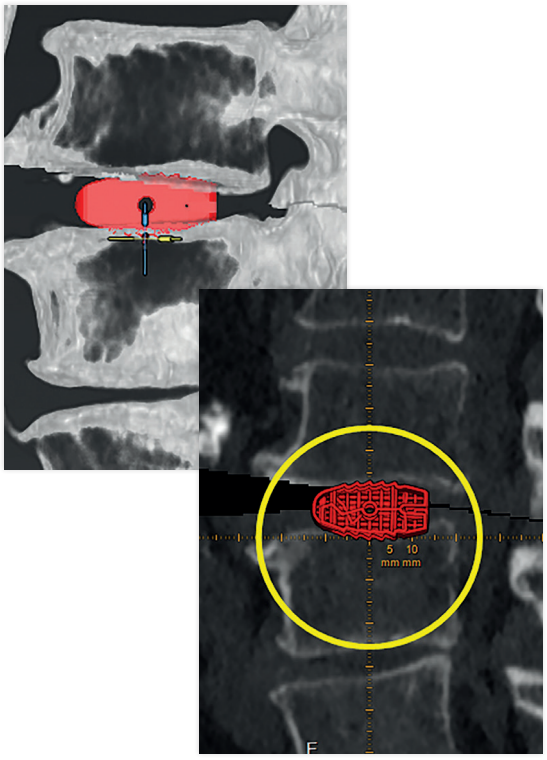
All selected and used implants are documented in the structured results list, including all relevant parameters, and can then be used for further planning and pre-operative preparation.

Thanks to more than 15 years‘ collaboration with numerous implant manufacturers around the world, **mediCAD® 3D Spine** includes the most up-to-date knowledge and an implant database that is updated and added monthly.

Spondylodesis / Placement of cages

mediCAD® 3D Spine offers a convenient, innovative, and easy-to-use solution for planning a spondylodesis.

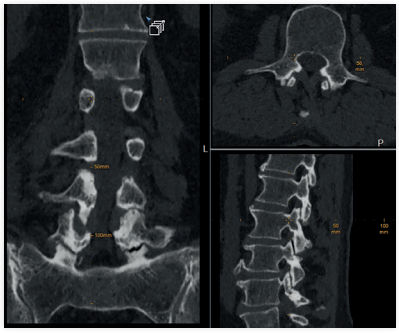
You are guided by a built-in wizard and (ideally in conjunction with sagittal balance and osteotomies that have already been performed) can simulate the restoration of a healthy patient anatomy. Once you have selected all required vertebrae and pedicle sides, you can automatically insert all the necessary screws and rods. All screws and rods inserted automatically with this function are documented in the structured results list, including all relevant parameters, and can be used for further planning and preoperative preparation.



General image functions

In addition to its pioneering functions for joint preservation and joint replacement, **mediCAD® 3D Spine** is proven to simplify the daily hospital routine of planning and dimensioning orthopedic spine procedures. Our software helps you to save a great deal of time on work that would otherwise be necessary. This means you have much more time to spend advising your patients and actually preparing for the surgery itself.

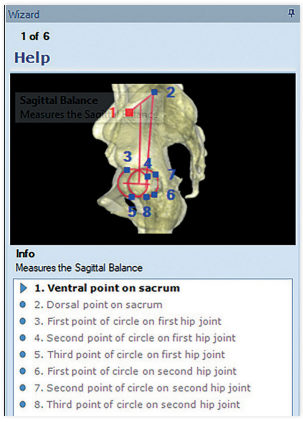
Visualization



Every image and plan is unique and pursues a different objective and demands a new approach. This means it is sometimes necessary to display image data from various points of view.
mediCAD® 3D Spine offers a wide range of different visualization options to address this challenge.

- Automatic depiction of individual 2D slices in the axial, sagittal and coronal plane.
- Option to display the 3D model from multiple different angles at the same time.
- Option to display and hide organs and tissues.
- Option to look “inside” the patient allows you to consider their vascular and muscular pathways.
- Surfaces can be displayed with various filters and parameters.
- You can choose to display, hide or focus on individual vertebrae, display them as a cropped image or to highlight them in color.

Assistant / Interactive help

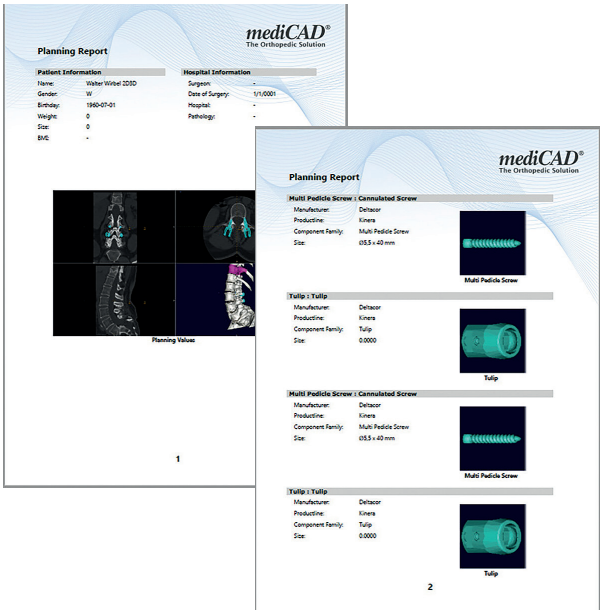


An intuitive support tool was implemented to highlight the innovative and simple operating concept of **mediCAD® 3D Spine.**

The assistant supports you step by step with the preparation for your plan. It guides you through the selection of the planning mode, local search, image selection and finally x-ray image scaling or segmentation of your 3D model. Tutorial videos are provided to ensure better understanding. And interactive help is available at all times during your planning process. This helps you with the schematic representation and a list of all of the steps to be carried out. Informative texts and images of the relevant areas and functions being used are also highlighted in a clearly understandable manner. This means, you always have all of the supporting information you need at a glance, facilitating and accelerating your work. The connection to Thieme eRef allows doctors to receive case-related, comprehensive, medical information from current literature anytime during their digital operation planning process.

Other functions

Planning report



mediCAD® not only provides a convenient PACS connection and audit-safe storage for your planning work, but also lets you save or print your work as a report.
Once the planning is complete, the software creates a structured report in which all the relevant information, such as patient ID, dimensioning and planned implants, is displayed and listed. You can then use this report to discuss your planning with colleagues or patients, saving time and enabling greater transparency and certainty.

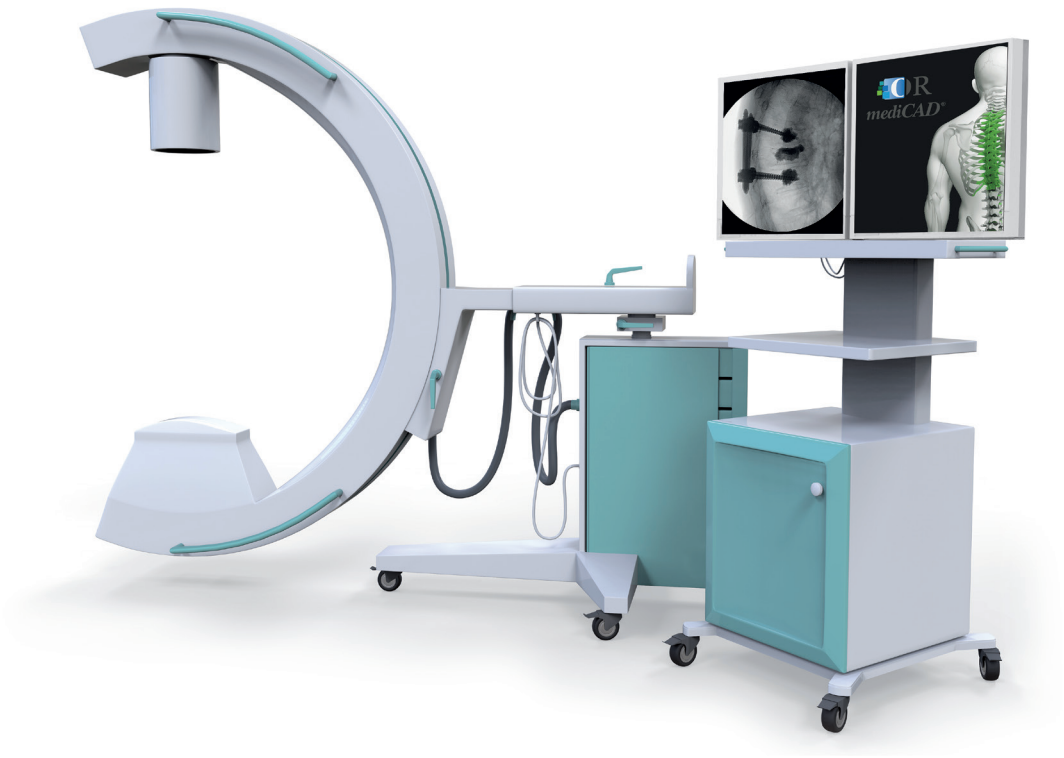
mediCAD® Services / 3D Printing

It will soon be possible to access further mediCAD Hectec GmbH services direct from the **mediCAD®** software. mediCAD Hectec GmbH's new service portal, **mediCAD® Services**, will be your port of call, be it for ordering 3D prints, preparing customized implants or logistics projects.

The first service to become available is provided by **mediCAD® 3D Printing**, which will allow you to order a 3D model of a previously segmented bone structure based on your planning direct from **mediCAD® 3D Spine**.

As the software is directly integrated into **mediCAD®**, requests for services are forwarded to **mediCAD® Services** (services.mediCAD.cloud). The ordering process for a 3D print is straightforward and systematic, and the model is shipped to you within a maximum of five working days (for recipients in Germany).

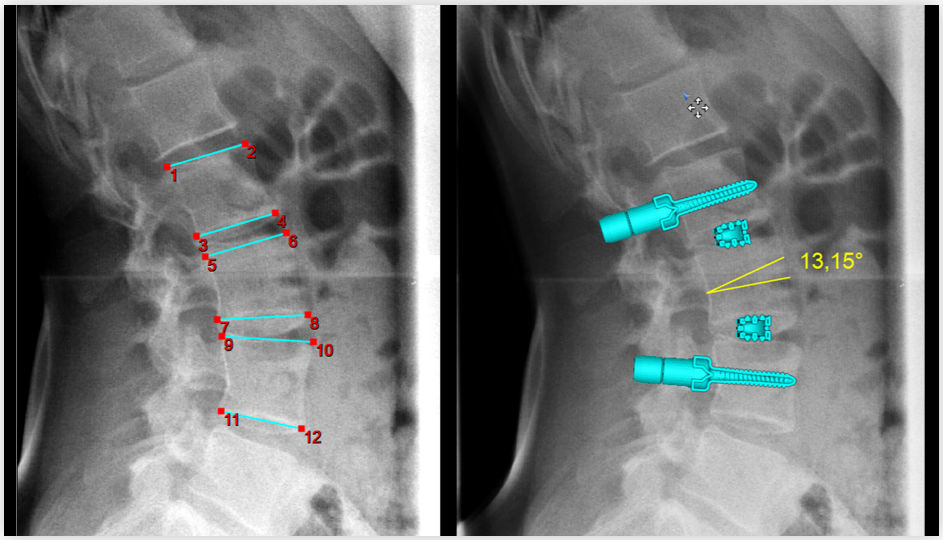
mediCAD® OR



mediCAD® OR Spine is a pioneering and powerful interoperative planning and matching software for interoperative assessment of orthopedic spine procedures.

Advantages:

- Intraoperative matching of the **mediCAD® 3D Spine** planning with live images the mobile C-Arm
- 3D imaging of the mobile C-Arm supports the intraoperative quality control
- **mediCAD® OR** is directly available on the mobile C-Arm during surgery
- Deviations from target and actual values are directly shown in **mediCAD® OR**



Manufacturer information

mediCAD Hectec GmbH
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DE- 84028 Altdorf

Hardware recommendations
mediCAD® 3D Spine requires Windows 7-10, 64-bit with. NET Framework 4.6.1 and an up-to-date processor with a minimum of 4 x 2,6 GHz and at least 8 GB RAM. The recommended display resolution is 1920 x1080 – FULL HD. A diagnostic monitor is not required.

Templates
We are happy to integrate your preferred manufacturers' implants and accessory templates into the system. Please contact us for further information.

Introduction / Training
mediCAD® 3D Spine requires no previous knowledge of the program and is easy to learn. The user is guided intuitively through the program with all instructions displayed in plain language on the
interface. Training usually requires approximately 3-4 hours.

mediCAD Hectec offers you skilled training sessions for every module. Both on-site and online training are available. X-ray images are imported into DICOM® format via an interface on your PAC/RIS system. **mediCAD® 3D Spine** communicates with all DICOM® interfaces, making it compatible with any PAC system. Many common image formats can also be imported.

Demo version
Order your free demo version of **mediCAD® 3D Spine**. The demo version corresponds to the full version of the program and is valid for 90 days. There are no restrictions on the functionalities or the implant database in the demo version.

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