# exocad



# exocad GmbH

# Information Implant Library Service

# exocad.com



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# exocad Library Services

exocad's constantly expanding verified component library databases contain a leading number of supported dental components. It is important to support the newest dental innovations right from the start. That's why we support our partners, official resellers and dental component manufacturers to make the integration process of new and updated component systems as easy and efficient as possible.

Our services take care of tasks like library creation, validation and integration into our software platform and includes exocad's thorough manual testing process that is unique to exocad's approach of *Quality First*-libraries. It is ideal for partners who want to focus on their core competencies and do not want to bother learning exocad library concepts.

We offer the following services. Additional services are planned and will be announced in the future.

- 1 CAD Component Library Services for *DentalCAD* & *ChairsideCAD*
- 2 Implant Library Service for exoplan
- 3 Surgical Component Library Service for exoplan Guide Creator
- 4 Tooth Library Service for *DentalCAD FullDenture*
- 5 Material Library Service
- 6 Partner Software Branding (postponed)

#### 7 Technical Consulting

This document covers the workflow for one service. Refer to our separate price list document for pricing information and further service details.

# 2 Implant Library Service (exoplan)

This service enables integration of your dental implants into our implant planning solution *exoplan*. We offer a service to create the necessary implant libraries based on the geometry data of the actual implants and additional information. We perform the checking, validation and integration of the finished library into our web-based download portal and in-software Library Manager. Once integrated, the library can be accessed by exocad users and your brand and products will be visible throughout our software systems. See the next chapter to learn about a few easy steps to get your implants integrated into *exoplan*.

#### 2.1 Service Details

Your assigned integration specialist will perform the following tasks during our services. Other tasks are not part of our standard update service and will require an individual offer based on the actual workload.

### 2.1.1 Implant Libraries - Initial Standard Creation (Order no. 2 C)

- STL Data & Parameter check
- Library creation up to 30 implants in multiple libraries (additional implants are subject to an extra fee)
- Library testing & validation
- Library file format conversion & Library signing
- Library integration (exocad download portal & exocad *Library Manager*)
- Announcement of availability via exocad News Bites newsletter

# 2.1.2 Implant Libraries - Standard Update (Order no. 2 U)

- Remove implants from library
- Adding FDA clearance information to library (if necessary)
- Modify tooth restrictions delete/change/add
- Reposition or addition of rotation marker
- Rename implant system or supplier, Replace supplier logo
- Changing the link from the supplier's website
- Update article numbers, color coding

#### 2.2 Initial Library Creation - How to get your implant data integrated

#### Obtaining your project ticket number

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We work with a ticketing system. We have sent you an email with this document via this system. It automatically assigns a ticket number to the project. Remember this ticket number for the following steps. Always use the reply function of your email program to answer our messages without changing the subject line of the email. This ensures the quickest response times as you stay within your defined project.

#### 2 Implant parameter list & product catalogs

Download the Excel parameter list here: "exoplan\_Parameter\_List\_Implants.xls". Each line represents one implant. All mandatory columns must be filled in. This document is used to create your libraries and to perform internal validation and documentation prior to final integration. Parameters are explained in our specification: "exoplan\_Dimensions.pdf".

If you are using any protected brand name for your implants or your company name, make sure to enter the correct trademark or registered trademark symbol ( ${}^{\otimes TM}$ ) in the parameter list. exocad will not check the correctness of your submitted wording and cannot be held responsible for any violation of trademark rights in this context. Your latest product catalogs are required to check your data. Feel free to send any helpful additional documents as well. Send us your filled in parameter list and product catalogs to complete this step.

Note: If any of your submitted components are marketed in the U.S., fill in the correct 510(k) numbers for each implant in column A. Those implants will be made available for the *exoplan* U.S. version.

#### 3 Service Offer & Acceptance

Your integration specialist will create an offer for the Implant Library Service based on the given product catalogs and parameters. See chapter 2.3 for included services and refer to our price list for pricing information. Order the service by signing our offer via DocuSign. You can change the signing responsibility within DocuSign to assign the agreement to the correct person within your company: DocuSign: How to change signer.

# 4 License Agreement

To enable us to use your data within our software systems, it's required to form a License Agreement.

You will receive a second DocuSign link after signing the service offer. You can then review and sign the agreement. After that, DocuSign sends you the verified signed PDF Version. Ensure that the agreement is signed by the manufacturer who is also named as the manufacturer on the product packaging. Sign the License Agreement to complete this step.

#### 5 Medical device certification & UID / ID / DUNS / VAT

A valid ISO 13485 certification or comparable medical device certificates according to your country (certification must be valid for the manufacturer who is also named as the manufacturer on the product packaging) needs to be presented. A scan, PDF or picture attachment is sufficient.

We also need your UID / ID / DUNS or VAT number to register you as an official technology partner. See 2.6.4 for details. Send us your medical device certification and UID / ID / DUNS or VAT to complete this step.

#### 6 Submit implant shape geometries in correct coordinate system

Create the implant shape geometries (.STL files) or modify your existing geometries to meet our specification. The specification can be downloaded here: "exoplan\_Dimensions.pdf". All requirements for implant geometries can be found in section 1. It's important to strictly follow our specification. Please contact your integration specialist via our ticket system from Step 1 if you face problems in understanding our specification. We will provide you with a file upload link. Send us your shapes and data ownership confirmation (see note) to complete this step.

Note: When sending us your data, confirm that it contains geometries created and distributed by you and that the geometry is based on the actual geometry of an existing physical part. We need written confirmation that you own all rights to distribute the data as well as a confirmation that the geometries are not modified in scaling of length or diameter to avoid data theft as agreed upon in our license agreement.

#### 7 Optional: Test license for *exoplan*

If you want to test the final libraries, you can request a test license of our *exoplan* software. A reduced fee is charged for this license. To request or update your test license, send a separate email to integration@exocad.com with the subject: "Test license for library integration, ticket \*YourTicketNumberFromStep1\*". *exoplan* can be downloaded in our Secure Area in the section "Software". The login credentials will be provided when applying for an *exoplan* license.

#### 8 exocad Library Creation

Our integration specialists will create your implant libraries based on the given implant shapes and parameters. Implant shapes will be separated into libraries based on their system. If questions occur during the creation process, our specialist will contact you directly.

#### 9 Finalization by exocad Library Testing & Validation

All libraries for our medical device software *exoplan* undergo an in-depth internal testing and validation process. The process ends with securing your .stl files against alteration and signing your *exoplan* implant libraries to prevent unauthorized modification. This throughout internal testing process involves manual labor and is unique to exocad's approach of *Quality First*-libraries. Please understand that this process might take some time to get it right.

After the testing and validation process is finished your *exoplan* implant libraries will become available for download on our website and within *Library Manager*.

# 2.3 Standard Library Update - How to get your existing libraries updated

#### Notify us & obtain your update project ticket number

Remember your ticket number. Always use the reply function of your email program to answer our messages without changing the subject line of the email. This ensures the quickest response times as you stay within your defined project.

#### 2 Update implant parameter list & product catalogs

Update your already existing parameter list from previous projects and make sure to highlight all changes. Non-highlighted changes will be ignored. This document is used to update your libraries and to perform internal revalidation and documentation prior to final integration.

If you are using any protected brand name for your implants or your company name, make sure to enter the correct trademark or registered trademark symbol ( $^{\otimes TM}$ ). exocad will not check the correctness of your submitted wording and cannot be held responsible for any violation of trademark rights in this context.

Your updated product catalogs are required to check your data. Feel free to send any helpful additional documents as well. Send us your updated parameter list and product catalogs to complete this step.

#### 3 Service Offer & Acceptance

We will assign an integration specialist to you who will create an offer for the update based on the given information. See chapter 2.3 for included services and refer to our price list for pricing information. Order the service by signing our offer via DocuSign.

#### 5 Optional: Send us your updated implant shape geometries

We will provide you with a file upload link if you wish to update implant geometries. Send us your new and updated implant shapes to complete this step.

Note: When sending us your data, confirm that it contains geometries created and distributed by you and that the geometry is based on the actual geometry of an existing physical part. We need written confirmation that you own all rights to distribute the data as well as a confirmation that the geometries are not modified in scaling of length or diameter to avoid data theft as agreed upon in our license agreement.

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#### 6 exocad Library Update

Our integration specialists will update your implant libraries based on the given information. If questions occur during the creation process, our specialist will contact you directly.

#### 7 Library Testing & Validation

All our medical device software libraries undergo an in-depth internal validation and testing and validation process. The process ends with securing your .stl files against alteration and signing your *exoplan* implant libraries to prevent unauthorized modification. This throughout internal testing process involves manual labor and is unique to exocad's approach of *Quality First*-libraries. Please understand that this process might take some time to get it right.

After the testing and validation process is finished your *exoplan* implant libraries will become available for download on our website and within *Library Manager*.

# 2.4 Maximum partner waiting time limit

Every library service project has a maximum partner waiting time limit of **two (2)** months. If our integration specialist is waiting for a response to an email that is causing delay of the integration project for more than two months, the project will be canceled. Any further work needs a complete restart of the service, including the necessary fees. The exact date of the integration specialists' email is decisive. We will inform you one week before the waiting time is over. This time limit can be raised upon decision by the integration specialist.

## 2.5 Frequently asked questions

Visit this direct link to our Partner information website for our most up to date FAQs: https://exocad.com/integration/partnerinfo