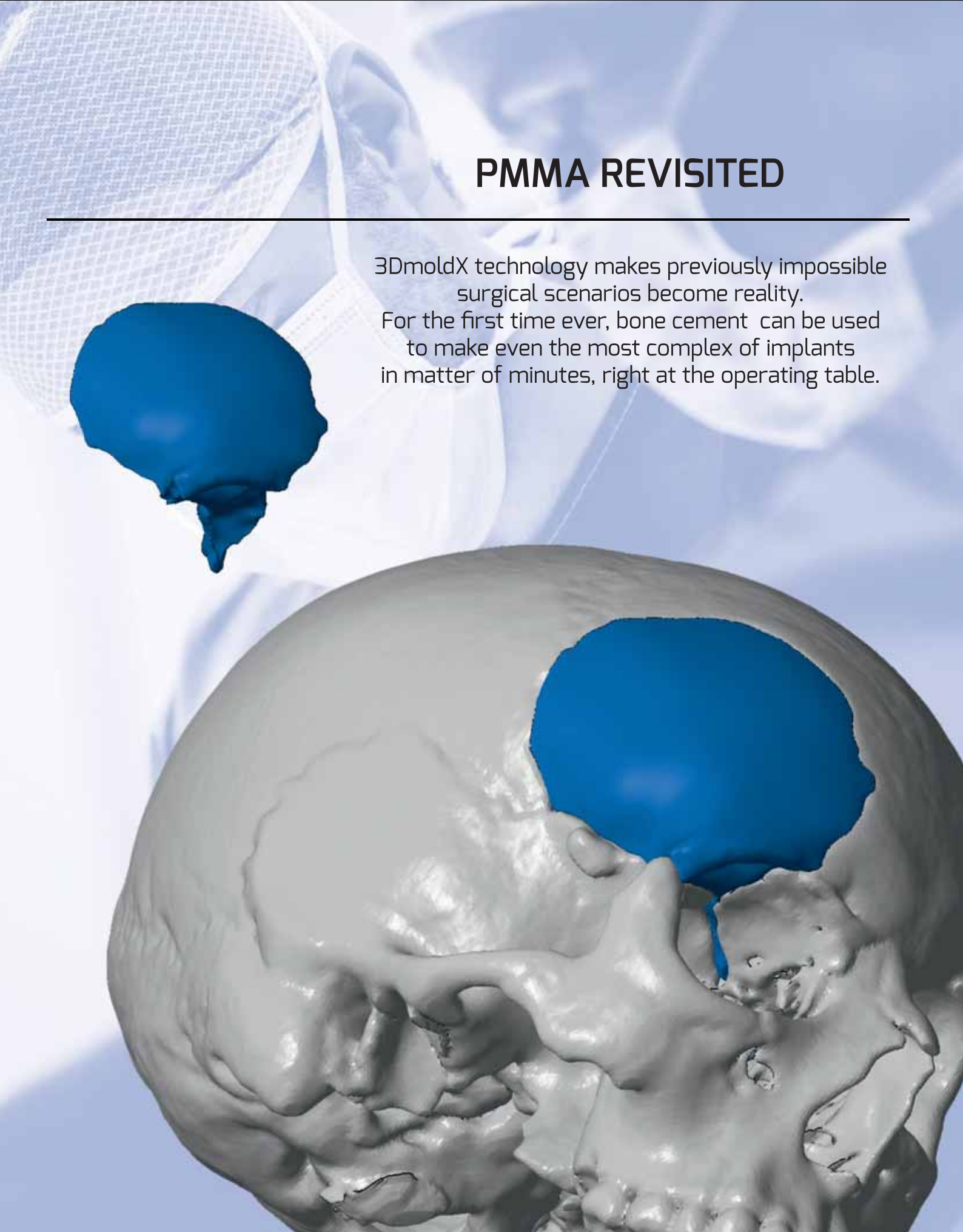


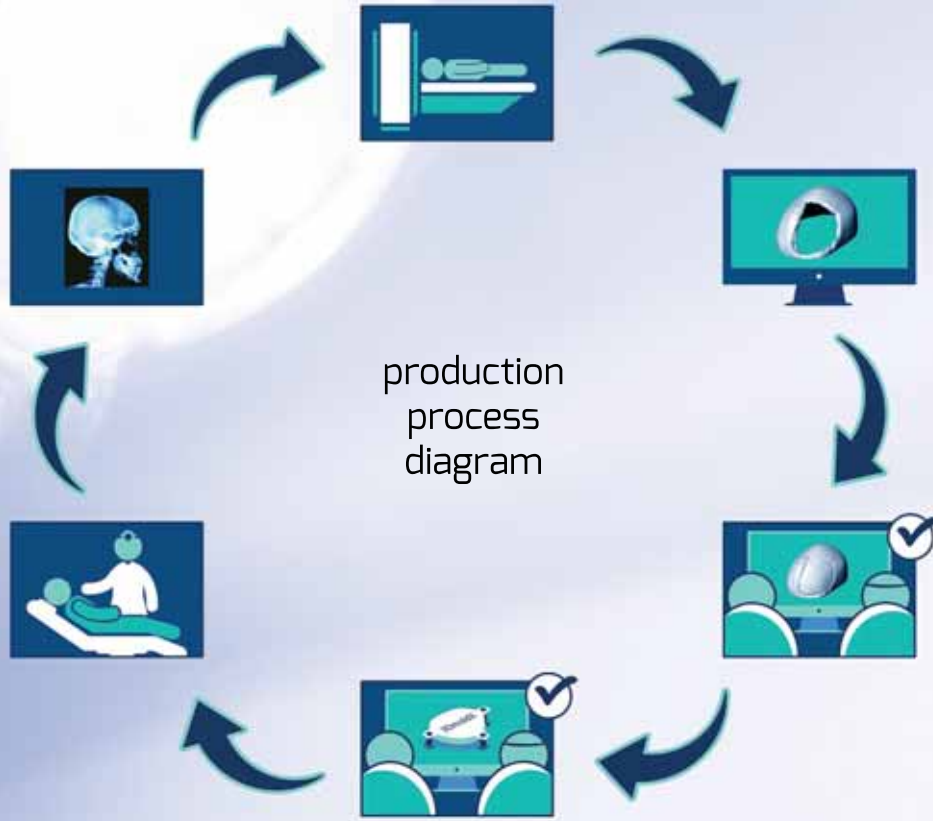
PMMA REVISITED

3DmoldX technology makes previously impossible surgical scenarios become reality.







For the first time ever, bone cement can be used to make even the most complex of implants in matter of minutes, right at the operating table.



How it's done. Our solution for PSI from bone cement.



Step by step procedures

<p>Process</p>  <p>Send us the patient's CT or MR scan in DICOM format.</p>	<p>Modelling</p>  <p>From your CT we create a computer model of your existing bone defect.</p>
<p>Reconstruction</p>  <p>We digitally reconstruct the bone defect in collaboration with the surgeon.</p>	<p>Creation</p>  <p>Once the surgeon has confirmed the shape and characteristics of the PSI (Patient Specific Implant), we go forward to create a unique 3DmoldX mold for a PSI, then 3D print the mold and deliver it to hospital. Alternatively, a 3DmoldX mold can be 3D printed in-house at the hospital if the necessary equipment is available.</p>
<p>Operation</p>  <p>At the hospital, before or during the operation, surgeon creates the PSI by pouring wet bone cement into our 3DmoldX mold and then goes forward with implanting it at the surgery.</p>	<p>Check-up</p>  <p>After the surgery is completed, you have a perfectly customized implant that fully aesthetically and physiologically removes your bone deformity with shorter operation time and much faster recovery.</p>

'The surgeon pours wet bone cement into a 3DmoldX mold, waits 5 minutes, peels the mold off and perfectly shaped patient specific implant is ready for immediate use'



Step by step how to make customized implants in 5 minutes.

1. Open mold



2. Pour in wet bone cement



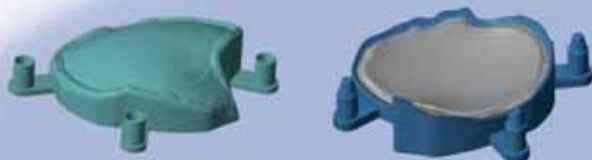
3. Press down



4. Wait 5 minutes



5. Open mold



6. Peel off mold



3DMoldX features and benefits

Precise fit

Our molds are designed to enable you to manufacture “drop-in fit” implants. Suture/drainage holes are made by the surgeon during the installation as needed. Bone cement implants are either 3.5, 4, 5 or 6 mm and tapered toward thin bone option is also available.

Sterilisation

3DMoldX molds are delivered non-sterile and must be sterilized before operation. See manual for sterilization requirements and re-sterilize the molds if it should ever become contaminated.

Modification

Bone cement implant may be modified by burring and drilling.

An example of an implant made according to our method



CATEH produces its custom-made medical devices for a particular user with additive technologies in a “Clean Room” designed according to the requirements for clean production and validated according to ISO 14644-1:2015 and the EU GMP standard of the purity class. The excellence we cherish for the application of additive technologies in medicine is also applied by our team to all our other users in the field of technique and everyday life. Influenced by the globalization of the market, and in order to maintain and improve the market position and increase competitiveness,

CATEH d.o.o. strives for excellence of products and services guided by the demands and expectations of customers. An essential basis for success in this direction are implemented quality management systems ISO 9001:2015 and ISO 13485:2016, all of which we have harmonised according to the relevant provisions and directives prescribed for medical devices made to order according to MDR (EU) 2017/745.

- 3DmoldX are custom made device.
All custom-made devices are exempt from CE-marking (see article 20 of the MDR (EU) 2017/745)
- We declare that this product complies with the general safety and performance requirements set out in Annex I to Regulation (EU) 2017/745. Regulation (EU) 2017/745 of the European Parliament and of the Council and REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 on medical devices.
- CLASSIFICATION: Class I
This non-invasive medical device is classified in Class I according to Annex VIII, Chapter III of the Classification Rules in Regulation (EU) 2017/745.
- 3DmoldX is supplied with a SPECIAL PURPOSE MEDICINAL PRODUCT STATEMENT, and individual 3DmoldX instructions for use.
Made in EU (Croatia)

Contact:

Need assistance or interested in a procedure?
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