



UBORA: Euro-African Open Biomedical Engineering  
e-Platform for Innovation through Education

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# Universal Splint

A splint with a basic design that is adaptable to any kind of articulation and articular problem and is capable of promoting mass-customization

# UBORA GROUP 4



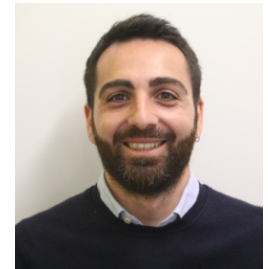
## GROUP MEMBERS



## UBORA MENTORS



Andrés Díaz Lantada



Carmelo De Maria



Janno Torop

# Clinical Need



Patients with ***broken and dislocated limbs sometimes benefit from immobilization***. Our device is aimed at immobilizing different limbs for providing a ***universal approach to articular problems***. It can be personalized to correct problems in the ankle, knee, wrist, elbow, neck and fingers. Intended users are ***children and adults with articular pathologies all over the world***.



# Existing solutions



Common solutions for articular immobilization include:

1. Plasters
2. Thermoformed materials
3. Polymeric-ceramic pastes



# Standard regulation



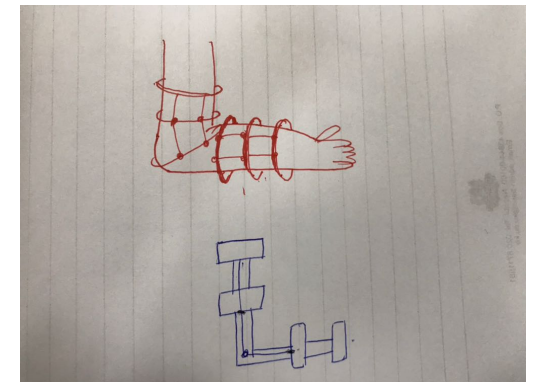
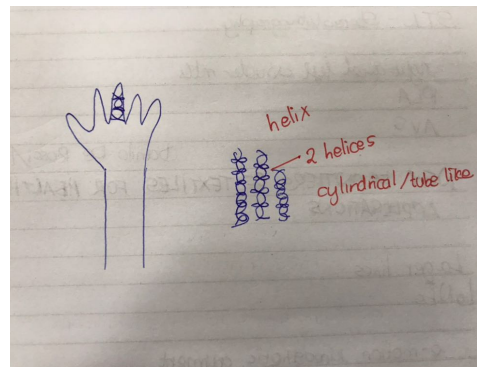
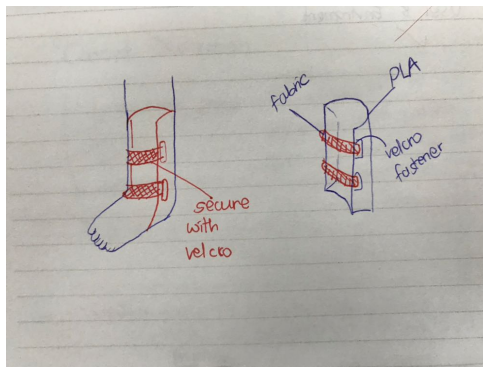
The following standards and guidelines are applicable to all devices, regardless the kind and risk classification:

Standard	Description
EN ISO 13485:2016	This standard specifies requirements for all entities involved in medical devices, in all stages of the product life cycle: from design to manufacture to installation to disposal. Ubora Platform is structured to be a guideline for design activities in compliance to this standard.
EN ISO 14971:2012	This standard specifies requirements for designers and manufacturers of medical devices, in order to minimize the risk of the device itself. There is no "risk zero" device but many activities can be implemented to reduce and manage risk. This standard provides useful checklists and also guidance on the most widespread risk management techniques such as FMEA.
MEDDEV 2.7.1 rev 4 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	This guideline provides information on methods used to assess the clinical performance and the clinical benefit of a medical device. It is provided for free by the Commission at <a href="http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native">http://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native</a> .
IEC 62366-1	This standard provides guidance on how to manage the human factors while designing a medical device (usability engineering). NOTE: chapter -2 of this same standards will provide comments and integrations
EN ISO 15223-1:2016	This standard lists a series of symbols that may be applicable in labels of medical devices

# Our proposal



Basic physical principle is having a **material resistant enough to immobilize the damaged articulation, while allowing some extent of deformation** for improved healing and comfort. Main sub function is structural, but interaction with the skin is also considered and improved via controlled **porosity**. The attachment to the articulation is another sub function to be solved by alternative principles, including the use of *straps, Velcro and mechanical joints among the components of the splints.*





# Advantages

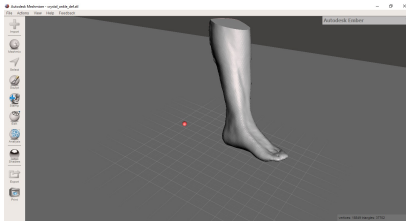


- Withstand mechanical demands depending on the articulation
- Material resistant enough to immobilize the damaged articulation
- Allow deformations up 10-20% for improved adaptation and healing.
- Washable
- Breathable

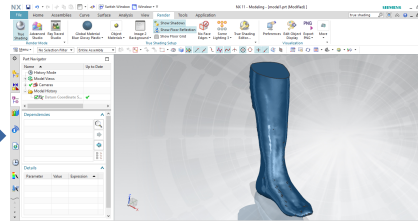
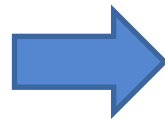
***The device is class I***



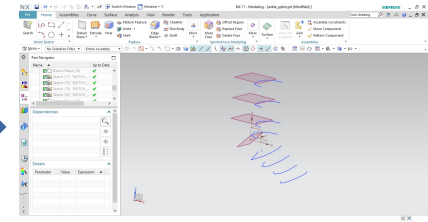
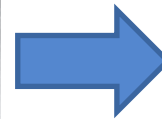
# Process



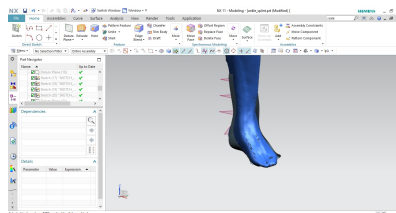
*Scanning*



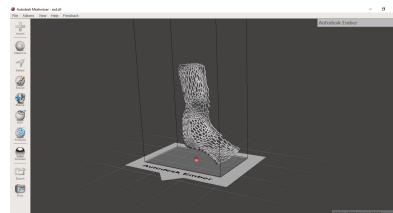
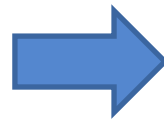
*CAD Programme*



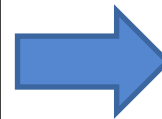
*Designing procedure*



*Assembly*



*Voronoi pattern*





# Ubora's platform



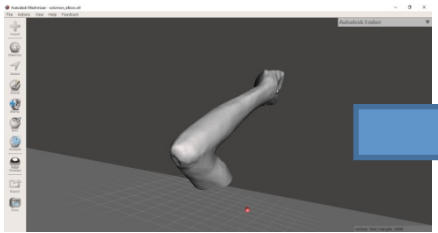
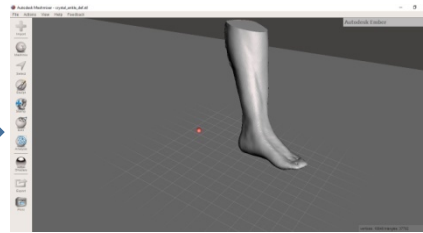
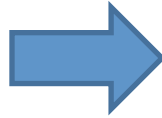
The screenshots illustrate the Ubora platform's functionality across different stages of a project:

- Dashboard - UBORA:** Provides an overview of the project, including a search bar, navigation tabs, and a 'Medical tags' section for 'Universal Splint'.
- Voting - UBORA:** Displays a grid of design sketches (Ankle 1, Ankle 3, Finger sketch 2, Elbow, Elbow 2, Finger sketch 1, Ankle 2) and their scores, allowing for community voting.
- Members - UBORA:** Lists the project members, including Crystal Emende, Rosa Lotano, Adrian Martinez, Andres Diaz Lantada, Solomon Kindie, Janmo Torop, DAVID SAY, and Carmelo De...
- Purpose designed part:** Shows a section for 'Purpose designed part' with a list of parts and a 'Feedback' button.
- Instructions for fabrication of prototypes:** Provides detailed instructions for the fabrication process, including a process flow diagram and a 'Feedback' button.

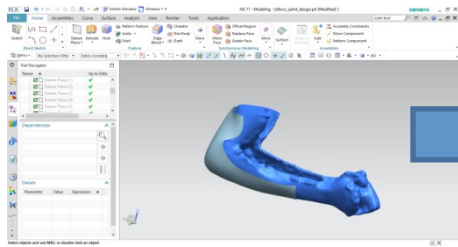
## Summary of the process and developed applications

I. Personalization starting from digitalization using optical scanner (Kinect)

II. Reconstruction and connection with CAD using Skanect free version

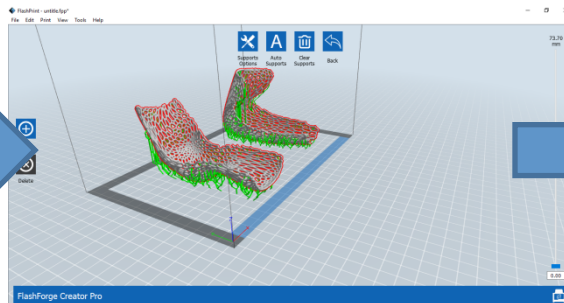
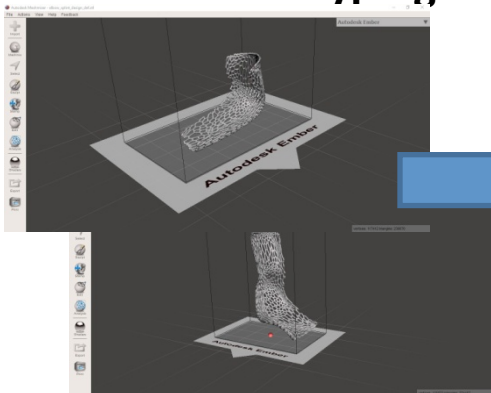


III. Computer-aided design of personalized geometries using parametric design



IV. Design of mesh-like / porous structures for enhanced performance

V. Prototyping and testing for concept validation



# Thank you for your attention

