

Requirements	Evaluation	Fulfilled?
Functional requirements:		
The device should immobilise the fractured limb (avoid secondary displacement and non-union)	Cannot directly be tested but large movements can be observed.	Not fulfilled, play in the device
The device should be adaptable to the patient and the swelling	<ul style="list-style-type: none"> Sizes of the human and the oedema are determined/ calculated Fit to different people can be tested with healthy participants 	Fulfilled, calculations made Fulfilled, participants fit the device Fit swelling, untested
Performance criteria:		
<i>Comfort</i>		
The intra-cast pressure should not cause harm to the patient, maximum of 32 mmHg	<ul style="list-style-type: none"> Test with pressure sensors between cast and skin of healthy participants Calculate 	Undetermined
The wrist angle should be right for the most common wrist fractures, at least between -20 ° and +30 °	Directly from the design	Fulfilled
The device should not cause skin irritation to the patient (not more than fibreglass, this could include ventilation)	<ul style="list-style-type: none"> Skin irritation (short term) could be evaluated with healthy participants Maybe material is tested before, search literature 	Fulfilled, no skin irritation. But some indents
The device should fit individual patients (can be build patient specific or adaptable)	Fit on healthy participants	Fulfilled, participants fit the device
The temperature in the cast should not exceed 45° during application and 37° during use	No chemical reaction takes place, and no heat is needed	N/A
Weight should be less than for a plaster cast (0.8-1.5kg), so at least less than 1 kg, aim for less than 500 gram	Evaluate with materials and volumes (SolidWorks)	Fulfilled, less than 500 grams
The cast should not offset the arm more than 50%, preferably less than 1.5 cm	Can be directly determined from the design for the smallest sizes	Not fulfilled, offset at the corners is larger
The device should not have sharp edges	Can be directly seen in the device	Fulfilled
<i>Protection</i>		
The device should resist an external force of at least 20N	Calculations on parts that are most at risk and the weakest parts	Undetermined
The cast should be hygienically better than plaster (avoid bacteria and mould from growing). This includes a waterproof and cleanable material and a design without small ridges and holes where dirt can pile up.	<ul style="list-style-type: none"> Ask an expert Literature on material 	Fulfilled/ undetermined, as far as it is known it is fulfilled

In case of failure of the cast, this should be clear to the user (so he can go to the hospital) Failure that induces an unnoticed risk should be avoided	Test failure	Undetermined, It presumably breaks or falls apart
<i>Sustainability and lifetime</i>		
The device should be more sustainable than currently used methods (considering the full life cycle: materials used, manufacturing, disposal)	Research materials, manufacturing and reusability	Fulfilled
The cast should last for at least 6 weeks on the patient	Cannot directly be tested but materials and impacts can be discussed	Undetermined
At the end of the product's lifetime (possibly after multiple uses: adapting, wearing and cleaning) the device should be recyclable meaning the product should be disassembled and the materials should be recyclable	Research materials and recyclability	Fulfilled
<i>Implementation to healthcare system</i>		
Hospital personnel should not need to do an very extensive training (max 1 day)	<ul style="list-style-type: none"> • Ask an expert • Test with healthy participants • Write application guide 	Undetermined
The time to produce/customise the device (with patient and clinician present) should not be more than 30 minutes	Test with healthy participants	Fulfilled, less than 10 minutes
The tools needed for production and/or application should be available in a hospital setting or feasible to buy (<€500)	Can be determined from the design directly (maybe ask hospital)	Fulfilled, only hex keys
The price of the cast should be low enough (<€50 = not more then 3x the price of fibreglass) Preferably the cast is between 3 euros (plaster cast) and 25 euros per patient	Prices of materials or parts can be determined	Undetermined, with material costs only fulfilled.
<i>Maintenance</i>		
The cast should be removable by a clinician	Can be determined from the design directly	Fulfilled
The device should be adaptable by the clinician (possibly also by the patient)	Can be determined from the design directly	Fulfilled
In case the device can be used multiple times the device should be cleanable at 100° Celsius or it should be resistant to a disinfectant.	<ul style="list-style-type: none"> • Research materials • Ask clinical cleaning expert 	Undetermined
<i>Regulations</i>		

The device needs to comply with the medical device regulation (European)	Look up medical device regulations and evaluate as far as possible	Class one device. N/A at this stage
The effectiveness of the cast should be extensively tested . This will be mechanical tests and simulations, short comfort tests with healthy volunteers and extensive clinical testing (not part of this research)	See other tests	N/A
<i>Inclusivity and social implications</i>		
The product should fit (or possible to be adapted to) 90% of the Dutch populations, P5 – P95	Test the fitting with healthy participants Calculation	Fulfilled according to calculations. Not determined in tests
The device should mark an injury. (Plaster or fibreglass casts mark clearly a broken bone (or other injury) a new type of cast might not have this. It could be useful to have this direct implication so people take into account the patients injury.)	Directly determined from device	Fulfilled
Wishes:		
The device should immobilise the limb as well as possible	From prototype	Not very good due to play (and additional rod)
The device should fit the specific patient as well as possible	Test with participants	The participants fitted the device
It should be easy to adapt the device to the specific patient and to swelling	Test with participants	Adapting for the participants was relatively easy, adapting for swelling is undetermined
The device should resist external forces as well as possible	See above	Undetermined
The cast should be as compact as possible (close to the arm and not limiting movement)	See above	Bad, too much offset in corners
Air ventilation is possible	Directly determined from device	Good, partly open device, limited in pad locations
Application of the cast should be easy and only a limited amount of training is required	See above	Application is quick, training time undetermined
The device should be as sustainable as possible	See above	Good
The cast should be reusable for multiple patients, as many times as possible	Ask expert	Reuseable, but undetermined for how many cycles
The device should be as cheap as possible	See above	Material cost €25,68

The investment for the hospital for equipment required to make the device should be as low as possible	Prices can be calculated	Not determined, investment in
The hygiene of the device should be as good as possible.	See above	Fulfilled/ undetermined, as far as it is known it is fulfilled
The cast should be as lightweight as possible	See above	Good, 395 grams
The cast should be water-resistant	Research materials	Fulfilled
The cast should be aesthetically pleasing (better than a plaster cast)	Ask healthy participants	Not fulfilled, participants like plaster
The device can be used in combination with x-ray (or easily be removed for x ray)	Research radiolucency of materials, x-ray angles	Undetermined
Visual inspection of the skin is possible	Directly determined from device	Good, partly open device so yes, other parts can be (partly) loosened
The cast can also immobilise unstable of displaced fractures	Not possible to test	N/A
The device is adaptable without removing the device or compromising immobilisation	Directly from device	Fulfilled
The device distributes the pressure on the limb	Directly from device	The pressure is distributed over the pad area
The device should cause the least possible amount of skin irritation	See above	Fulfilled, no skin irritation. But some indents
The device is new and does not exist yet	Patent search	Similar working principles but a very different design

Hygiene:

“Care and attention that is given to keeping yourself and your environment clean, especially to prevent disease”

- Can be worn while doing personal hygiene procedures (washing hands, shower)
- Material does not hold more dirt/ germs etc. than the skin
- Waterproof and soapproof
- Clean at high temperature and/or with disinfectant after a person has used it