

Requirements	Evaluation	Fulfilled?
<b>Functional requirements:</b>		
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"> <li>Sizes of the human and the oedema are determined/ calculated</li> <li>Fit to different people can be tested with healthy participants</li> </ul>	Fulfilled, calculations made Fulfilled, participants fit the device Fit swelling, untested
<b>Performance criteria:</b>		
<i>Comfort</i>		
The intra-cast <b>pressure</b> should not cause harm to the patient, maximum of 32 mmHg	<ul style="list-style-type: none"> <li>Test with pressure sensors between cast and skin of healthy participants</li> <li>Calculate</li> </ul>	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 <b>skin irritation</b> to the patient (not more than fibreglass, this could include ventilation)	<ul style="list-style-type: none"> <li>Skin irritation (short term) could be evaluated with healthy participants</li> <li>Maybe material is tested before, search literature</li> </ul>	Fulfilled, no skin irritation. But some indents
The device should <b>fit individual</b> patients (can be build patient specific or adaptable)	Fit on healthy participants	Fulfilled, participants fit the device
The <b>temperature</b> 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
<b>Weight</b> 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 <b>offset</b> 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 <b>sharp</b> edges	Can be directly seen in the device	Fulfilled
<i>Protection</i>		
The device should resist an <b>external force</b> 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"> <li>Ask an expert</li> <li>Literature on material</li> </ul>	Fulfilled/ undetermined, as far as it is known it is fulfilled

In case of <b>failure</b> 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 <b>sustainable</b> than currently used methods (considering the full life cycle: materials used, manufacturing, disposal)	Research materials, manufacturing and reusability	Fulfilled
The cast should <b>last</b> 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 <b>recyclable</b> 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 <b>training</b> (max 1 day)	<ul style="list-style-type: none"> <li>• Ask an expert</li> <li>• Test with healthy participants</li> <li>• Write application guide</li> </ul>	Undetermined
The <b>time to produce/customise</b> the device (with patient and clinician present) should not be more than 30 minutes	Test with healthy participants	Fulfilled, less than 10 minutes
The <b>tools</b> 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 <b>price</b> 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 <b>removable</b> by a clinician	Can be determined from the design directly	Fulfilled
The device should be <b>adaptable</b> 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 <b>cleanable</b> at 100° Celsius or it should be resistant to a disinfectant.	<ul style="list-style-type: none"> <li>• Research materials</li> <li>• Ask clinical cleaning expert</li> </ul>	Undetermined
<i>Regulations</i>		

The device needs to comply with the <b>medical device regulation</b> (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 <b>tested</b> . 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) <b>90%</b> 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 <b>immobilise</b> the limb as well as possible	From prototype	Not very good due to play (and additional rod)
The device should <b>fit</b> the specific patient as well as possible	Test with participants	The participants fitted the device
It should be <b>easy to adapt</b> 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 <b>compact</b> as possible (close to the arm and not limiting movement)	See above	Bad, too much offset in corners
<b>Air ventilation</b> is possible	Directly determined from device	Good, partly open device, limited in pad locations
<b>Application</b> 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 <b>sustainable</b> as possible	See above	Good
The cast should be <b>reusable</b> for multiple patients, as many times as possible	Ask expert	Reuseable, but undetermined for how many cycles
The device should be as <b>cheap</b> as possible	See above	Material cost €25,68

The <b>investment</b> 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 <b>hygiene</b> 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 <b>lightweight</b> as possible	See above	Good, 395 grams
The cast should be <b>water-resistant</b>	Research materials	Fulfilled
The cast should be <b>aesthetically</b> pleasing (better than a plaster cast)	Ask healthy participants	Not fulfilled, participants like plaster
The device can be used in combination with <b>x-ray</b> (or easily be removed for x ray)	Research radiolucency of materials, x-ray angles	Undetermined
<b>Visual</b> 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 <b>unstable</b> of displaced fractures	Not possible to test	N/A
The device is <b>adaptable</b> without removing the device or compromising immobilisation	Directly from device	Fulfilled
The device <b>distributes the pressure</b> on the limb	Directly from device	The pressure is distributed over the pad area
The device should cause the least possible amount of <b>skin irritation</b>	See above	Fulfilled, no skin irritation. But some indents
The device is new and <b>does not exist</b> 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 soaproof
- Clean at high temperature and/or with disinfectant after a person has used it