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2 **Title:** Environmental sustainability of orthopaedic devices produced with powder bed fusion

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10 **Keywords:** life cycle assessment (LCA), product lifetime, industrial ecology, Additive
11 manufacturing, Orthopaedic device, Traditional manufacturing

12
13 **Abstract:**

14 Additive manufacturing consists in melting metallic powders to produce objects from 3D data,
15 layer upon layer. Its industrial applications range from automotive, biomedical (e.g. prosthetic
16 implants for dentistry and orthopedics), aeronautics and others.

17 This study evaluates the possible improvement in environmental performance of laser-based
18 powder bed fusion additive manufacturing systems on prosthetic device production through Life
19 Cycle Assessment (LCA) methodology. Environmental impacts due to manufacturing, use and end
20 of life of the designed solution were assessed. In addition, two powder production technologies, gas
21 atomization (GA) and plasma atomization (PA), were compared in order to establish the most
22 sustainable one. Production via traditional subtractive technologies and the additive manufacturing
23 production were also compared.

24 3D building was found to have a significant environmental advantage compared to the traditional
25 technology. The powder production process considerably influences on a damage point of view the
26 additive manufacturing process, however its impact can be mitigated if GA powders are employed.

27 **1 Introduction**

28 Additive manufacturing (AM) is a 3D building technology that is rapidly increasing among
29 manufacturing processes, in which the building process involves layering materials. Its strengths are

30 its ability to create objects with a high geometrical complexity, which are not possible to obtain in
31 traditional manufacturing, and the flexibility in meeting customer's requests in terms of design,
32 without increasing the productive costs.

33 Its aims are perfectly in line with the European Union Industry 4.0 plan (European Parliament
34 Research Service, 2015), which is built on the model of the high-tech strategy of the German
35 government, and whose main objectives are an increased flexibility and productivity in
36 manufacturing, mass customization and better quality.

37 In order to achieve these ambitious goals a new vision, named the "smart factory", is needed,
38 including the integration of IT services, such as the digitisation of information and big data analysis,
39 and of cyber-physical systems, such as embedded sensors, intelligent robots and additive
40 manufacturing devices.

41 Additive manufacturing has been designated by the Boston Consulting Group, the worldwide
42 multinational company in management consulting, as one of the five enabling technologies due to
43 increased efficiency in material use (Sirkin, Zinser & Rose, 2015).

44 Powder bed fusion (PBF) is one of the latest terminologies for the designation of an AM process
45 in which a metal powder layer is laid out over a bed and sintered by a high-energy beam, often a
46 laser (Gibson, Rosen & Stucker, 2015).

47 This technology can be applied to a wide range of materials, but is most suited to metals. The
48 opportunity to build metal objects with a complex geometry and high customization potential,
49 which is impossible in traditional manufacturing, is one of the most interesting features from a
50 technological, as well as a business perspective.

51 Selective laser melting (SLM) is one of the commonly used techniques, in which metallic
52 powder is fully melted in high-density and 3D structures (Gibson et al., 2015) rather than sintered,
53 thus giving greater control over material properties such as porosity and crystal structures.

54 Although the technical achievements of AM processes are widely acknowledged, they still need
55 a Life Cycle Assessment (LCA), in order to evaluate the strengths and weaknesses from a

56 sustainability perspective, in comparison with traditional manufacturing. A literature analysis was
57 therefore conducted and the main findings are reported below.

58 **1.1 Literature analysis**

59 As reported by Kellens et al. (2017), regarding AM processes as self-sufficient technologies is
60 not accurate, as post-processes are often required to reduce surface stresses due to the anisotropy of
61 AM parts.

62 The same authors provided a wide overview of AM processes compared to the corresponding
63 traditional manufacturing processes.

64 For example, Serres, Tidu, Sankare and Hkawka (2011), applied the Eco-Indicator 99
65 methodology (Goedkoop & Spriensma, 2001) to the production of a mechanical component in
66 Ti₆Al₄V alloy, and analyzed the incidence on total damage caused by upstream processes, such as
67 powder production and ingot production, on additive and traditional manufacturing. The authors
68 showed that the AM involves much lower damage compared to traditional manufacturing, however
69 the two technologies are comparable if larger parts are produced with the AM, due to the
70 considerable amount of metal powder needed to build the component.

71 Peng et al. (2017) applied a system expansion approach to the AM process to model the by-
72 product derived from unmelted loose powder at the end of the productive process. They considered
73 five environmental indicators, global warming potential, acidification potential, Chinese resource
74 depletion potential, eutrophication potential, and respiratory inorganics. They found that an impeller
75 made with titanium alloy totally produced with AM has a higher impact compared to that produced
76 with traditional manufacturing. This environmental damage is mainly due to powder production and
77 electricity consumption. AM may only have environmental advantages if the impeller is partially
78 produced with traditional manufacturing.

79 Priarone, Ingarao, Di Lorenzo and Settineri (2016) studied both productive processes (traditional
80 and additive manufacturing) from a cradle-to-grave perspective in terms of CO₂ emissions,
81 computed using the carbon emission signature (CES) method proposed by Jeswiet and Kara (2008),

82 and the energy demand by applying the system expansion with substitution LCI model. They found
83 that the environmental loads are influenced by the material removal rate - AM is the most
84 favourable technology when a significant amount of material can be saved, although there is a
85 higher energy consumption compared to traditional manufacturing when small quantities of
86 material need to be removed.

87 Huang et al. (2015) found that AM has a considerable advantage over traditional manufacturing
88 when different case-studies (EOS, 2013; Krailling & Novi, 2014; Munsch, Wycisk, Kranz, Seyda &
89 Claus, 2012; the SAVING project, 2009; Tomlin & Meyer, 2011) related to the production of
90 components for transportation vehicles, are considered and analyzed in order to outline a common
91 profile.

92 The use phase plays an important role in damage assessment. Considering a period from 2014 to
93 2050, AM parts are preferable to the traditional manufactured ones in terms of energy savings,
94 thanks to a significant mass reduction in the components, which entails a lower fuel consumption.
95 Moreover, lower buy-to-fly ratios of AM parts, which were assumed to be 1.5 for all AM processes,
96 in the cradle-to-gate LCI model resulted in lower primary energy use and GHG emissions compared
97 to traditional manufacturing.

98 In the medical devices production field, the following studies have been published, however
99 none of them involve a comparison with traditional manufacturing. Baumers, Tuck, Bourell,
100 Sreenivasan and Hague (2011) analyzed the energy consumptions of two laser sintering platforms
101 (Sinterstation HiQ+HS and EOSINT P 390) for building two prosthetic parts and found that most
102 energy is employed for heating and cooling.

103 Sreenivasan, Goel and Bourell (2010) calculated the energy consumption for producing
104 prosthetic parts using polymeric material by defining an energy indicator which enables different
105 selective laser sintering processes to be compared.

106 **1.2 Scope of the LCA study**

107 In this study LCA methodology was used to analyse the different levels of impact on the
108 environment of manufacturing hip prostheses using AM and traditional manufacturing processes. In
109 particular, femoral stems produced with Ti₆Al₄V alloy by Powder Bed Fusion technology and by
110 traditional manufacturing, over the whole life cycle, were considered.

111 Due to the relevance of metal powder production in terms of the total damage, gas atomization
112 (GA) and plasma atomization (PA) were compared, in order to evaluate the most sustainable
113 production method.

114 The advantages of AM compared to traditional manufacturing were also assessed through a
115 social indicator during the impact assessment stage which expresses the acquired utility of the part
116 produced with AM from a social perspective. In this study, the interest in the environmental
117 performance of the product is predominant over its technical performance, although this was taken
118 into account in the environmental analysis in order to provide a result as complete as possible.

119 **2 Life cycle of a femoral stem produced with PBF**

120 A hip implant is the only effective cure for coxitis, which is a degenerative disease in which the
121 cartilage surrounding the two extremities of the joint, femoral head and the acetabulum,
122 deteriorates.

123 In its primitive form, coxitis occurs in people over 60, while it can affect younger people due to
124 congenital illness, such as dysplasia (Gruppo Biompianti, 2017). In Europe more than 600,000 hip
125 replacement procedures were performed in 2005 (Kiefer, 2007).

126 The entire life cycle of femoral stems produced with AM was considered taking into account
127 Ti₆Al₄V alloy powder production, femoral stem production, use and end of life phases. The titanium
128 alloy production, titanium alloy powder (40 µm) production with atomization and the production
129 phase with an EOS M290 machine were included. Waste material disposal, such as waste metal
130 recycling and exhausted argon treatment, were also included.

131 During the production process, indoor emissions were taken into account, considering PPE
132 (personal protective equipment). The main steps in the life cycle of femoral stem production with
133 AM are described in Figure 1.

134

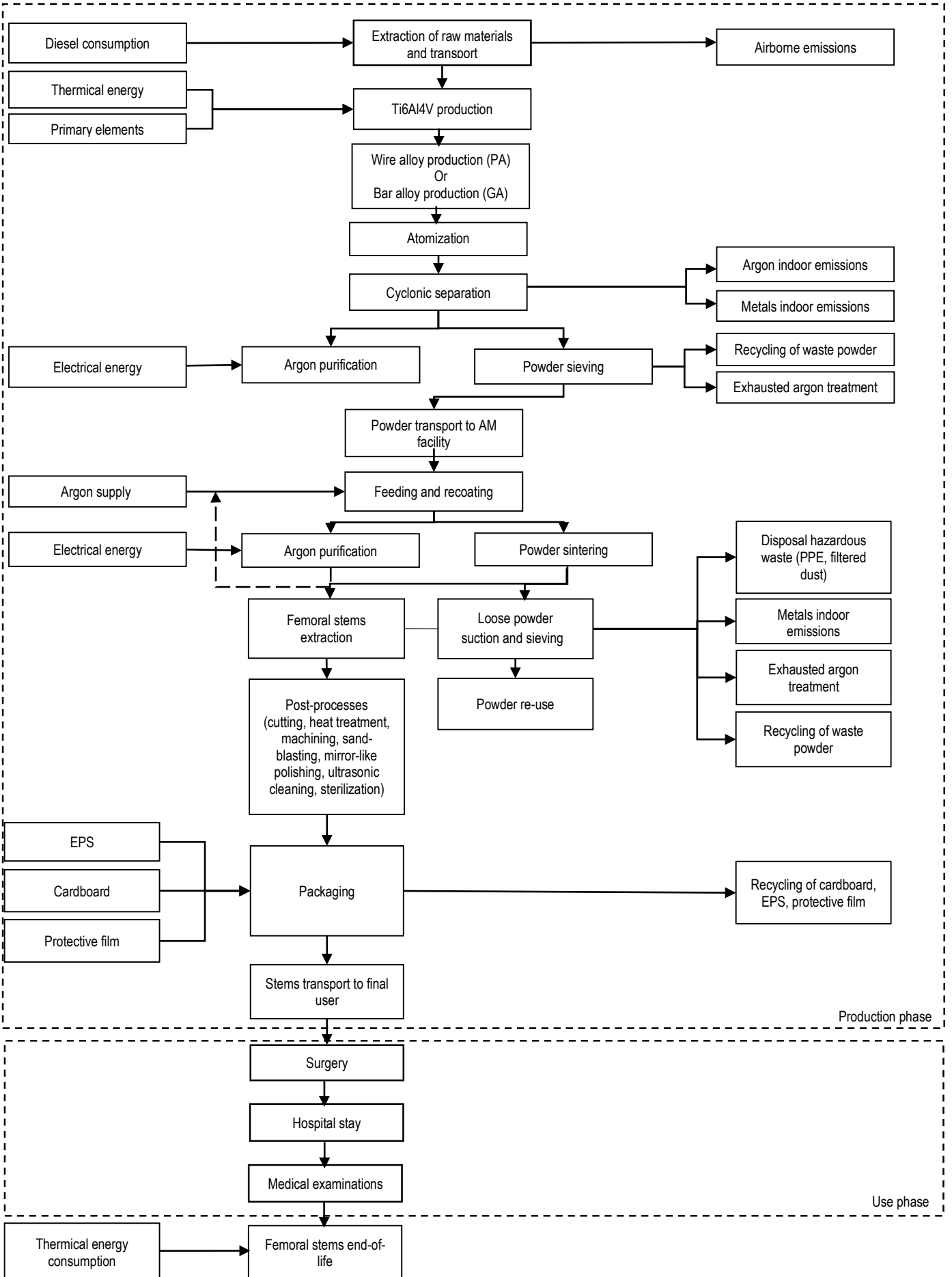


Figure 1 System boundaries of femoral stem life cycle with AM

136 **2.1 Ti₆Al₄V powder production**

137 Ti₆Al₄V powder production is described first considering the GA technology and then the PA.

138 The main differences between these production processes consist in alloy feeding and atomization
139 technology.

140 The PA process uses a Ti₆Al₄V wire feedstock, which is straightened and positioned at the apex
141 of three plasma torches. Each plasma torch provides about 30 kW (Pyrogenesis, 2017) and is fed
142 with argon. Cooling water is fed to each torch and to the atomization tower in order to ensure
143 accurate temperature control. The plasma flow melts the wire, whose droplets solidify into spherical
144 particles when they fall down the atomization tower.

145 The GA process uses a Ti₆Al₄V bar feedstock that is rotated and, at the same time, lowered into
146 an inductive coil which melts the bar without making contact with it. The melt is then atomized by
147 high-pressure argon jets.

148 Another important difference between the two technologies is the morphologic atomization
149 efficiency. Morphologic atomization efficiency is the capacity to produce high purity and high
150 sphericity of particles and it is mathematically defined as the ratio of perfectly spherical and pure
151 particles over the total amount of target powder.

152 PA technology is characterized by nearly 99% morphologic atomization efficiency, while, GA
153 technology has about 90% morphologic atomization efficiency. These efficiencies are estimated on
154 the basis of SEM images reported in Popovich, Sufiiarov and Grigoriev (2017).

155 The outgoing argon and powder flows, for both PA and GA technologies, are then separated by
156 the following steps:

- 157 • cyclonic separation of Ti₆Al₄V powder from argon;
- 158 • sieving of Ti₆Al₄V powder in order to accurately separate powder particles with the correct
159 particle size distribution and morphology for AM from oversized powder, which is supposed
160 to be sold to coating manufactures, and from undersized powder, which is supposed to be
161 sent to metal recycling process;

- 162 • baghouse filtration which purifies exhausted argon;
- 163 • argon recirculation in the atomization process.

164 The powder produced by PA technologies presents a tap density of 2810 kg/m³ (Advanced
165 Powder and Coatings Inc., 2017), while powder produced by the GA process has a tap density of
166 2710 kg/m³ (Venkatesh et al., 2016).

167 Both atomization processes work 16 hours/day (EOS, 2017) and are characterized by indoor and
168 local emissions of argon and metals.

169 **2.2 Femoral stem production**

170 Femoral stem production takes place in an EOS M290 machine, where fusion is performed by a
171 400 W laser. The production lasts 61 hours and 21 minutes with a production capacity of 20 femoral
172 stems (Poly-Shape, 2017) per job. After a set-up phase, in which argon is injected in order to
173 minimize the oxygen level, powder is fed by the dispenser system. A 40 µm thick layer is then
174 extended on a titanium plate with a recoater. Laser fusion involves the selective melting of cross-
175 sections, previously defined by the CAD model. After each layer has been completely melted, the
176 plate is lowered for a new layer deposition which, in turn, will also be melted.

177 During the build phase, the argon flow is insufflated in the process chamber in order to prevent
178 the development of an explosive atmosphere due to increase in powder particles and to control the
179 N/O pick-up. An air recirculating filtering system works continuously in order to guarantee the right
180 level of argon purification.

181 After the job has been completed, the parts are extracted by workers, who wear protective
182 equipment. Extraction involves the separation by sieving solidified parts from the remaining loose
183 powder, which are then reused for the following job. After extraction, the parts are heat treated for
184 two hours at 840° C, cut from the plate with a wire erosion machine and, then, finished with sand-
185 blasting and mirror-like polishing. As the parts produced have no internal cavities, depowderization
186 with compressed-air is not considered. Indoor metal emissions are considered, which occur during
187 the part extraction, machine cleaning and cutting of the stems from the building platform. Waste

188 metal powders resulting from machine cleaning and caught by protective equipment are rendered
189 inert first and then buried in a residual landfill.

190 **2.3 Use phase**

191 The use phase takes into account the surgical stem implantation, a hospital stay for two weeks
192 and medical examinations over the patient's lifetime. The average lifetime of the prosthesis is
193 calculated to be 14.5 years. This value was obtained with a weighted average of current hip joint
194 survivals, which range between 92% at 11 years and 86% at 22 years, as reported by Wyatt,
195 Hooper, Frampton and Rothwell (2014). It is assumed that the first medical examination occurs in
196 the initial weeks after the stem implantation with the second examination occurring in the same
197 year. In normal conditions patients undergo subsequent medical examinations every five years. The
198 medical check-up consists in X-ray examinations, which take 30 minutes, in order to evaluate the
199 effects of wear and tear on the prosthesis. If the patient lives beyond the lifetime of the prosthesis, a
200 surgical removal was considered. Deceases before the stem removal were defined as being equal to
201 25% of total implantations (rate of decease within 10 years from the stem's implantation,
202 Wainwright, Theis, Garneti & Melloh, 2011).

203 If death occurs before removal, the prosthesis is not removed from the patient, in order to
204 preserve the integrity of the person.

205 **2.4 End of life**

206 Femoral stem end of life was defined following direct interviews with technicians from an Italian
207 hospital, the Rizzoli Orthopaedic Institute. These technicians reported that prostheses are surgically
208 removed, sterilized and then archived. No material recycling or prosthesis reuse is performed,
209 according to practices adopted by interviewed technicians.

210 **3 Methods: Life cycle assessment**

211 **3.1 Goal and scope definition**

212 The goal of the study was to assess the environmental impacts of Ti₆Al₄V alloy based femoral
213 stems produced with AM over their entire life cycle in order to identify the environmental hotspots

214 of the system in line with UNI EN ISO 14040-14044 regulations and to propose improvements for
215 impact mitigation.

216 **3.2 System, functional unit and function of the system**

217 The system studied is a bed fusion of Ti₆Al₄V alloy powder. AM is used for the application of
218 biomedical devices, such as femoral stems. Twenty femoral stems produced with AM were
219 analyzed.

220 **3.3 System boundaries**

221 The system boundaries cover the entire life cycle of the analyzed system ranging from the
222 Ti₆Al₄V alloy feedstock and Ti₆Al₄V powder productions to the manufacture, use and end of life
223 stages of the femoral stems (Figure 1). The system boundaries of the femoral stem production using
224 traditional manufacturing are shown in Figure 2.

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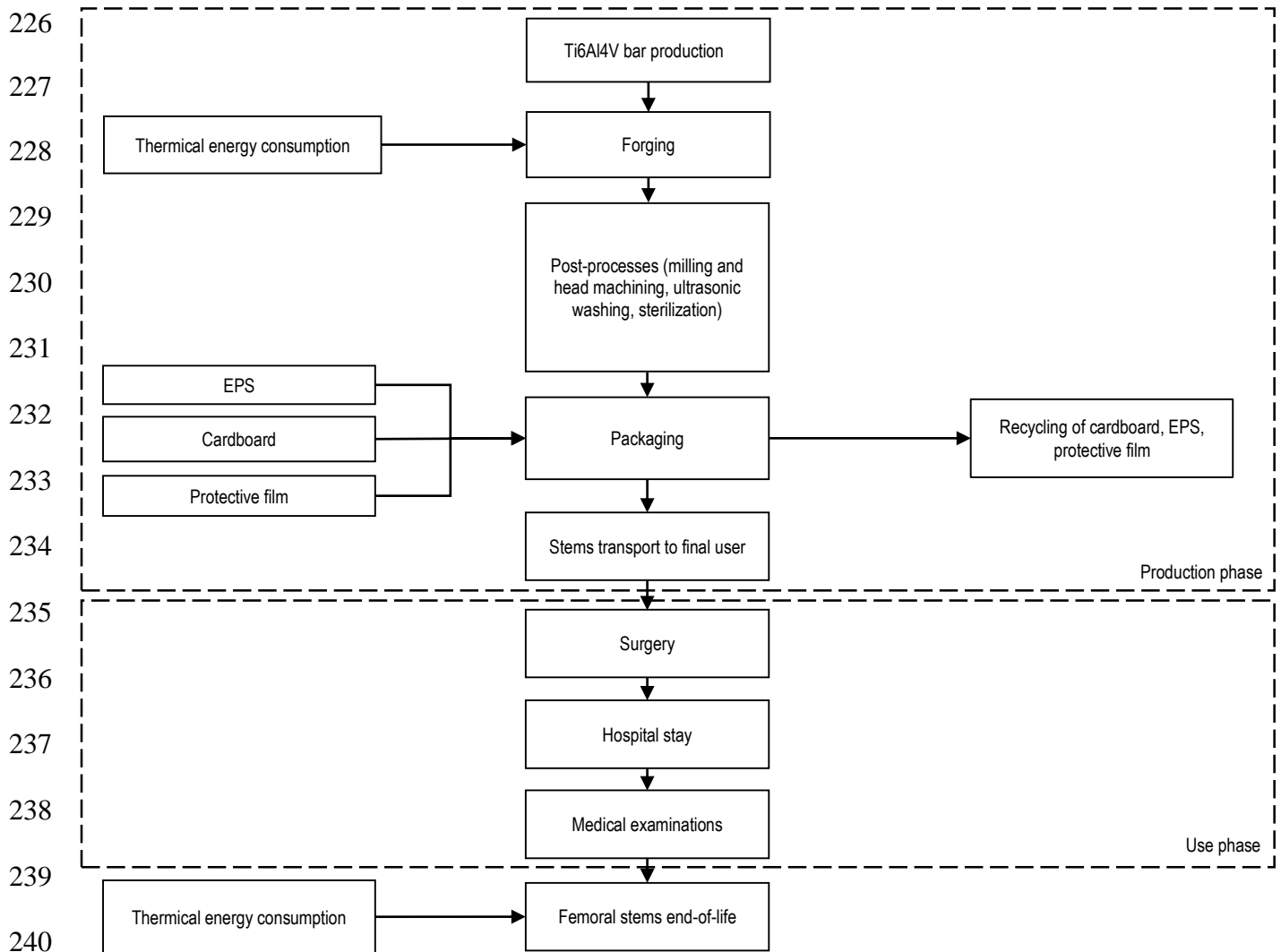


Figure 2 System boundaries of femoral stems life cycle with traditional manufacturing

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The production, maintenance and disposal of facilities as well as other auxiliary materials were also included in the present study. Air and indoor emissions as well as solid and liquid waste produced in each step were considered and quantified. The following assumptions were also made:

- Transport of raw materials, facilities, systems and machines are considered for an average distance of 100 km from the producer to the user, as required by the environmental product declaration (EPD) certification, when primary data about distances are not available;
- Distance of transport of femoral stems from the producer to the final customer is fixed at 100 km: 40% by rail and 60% by road;
- Electricity energy production is assumed to be the European mix electricity energy proposed by Ecoinvent database (Ecoinvent Centre, 2018);

- 252 • Installation of 99.97% efficiency HEPA air filter during femoral stem production and
253 powder production steps;
- 254 • Use of 99.95% efficiency personal protective equipment (filter category P3) during EOS
255 M290 machine cleaning, cutting, powder production and exhausted argon treatment steps
256 (EOS, 2016).

257 **3.4 Data quality**

258 Primary data related to the raw materials and to the AM process, the machine characteristics, the
259 consumables needed for the stem production (such as the amount of argon, while the amount of
260 powder is calculated on the basis of other primary data), the post-production treatments were
261 directly collected from a market leader in AM production in Europe.

262 Another market leader in Europe in prostheses produced by traditional manufacturing was also
263 interviewed. Use and end of life phases were modeled with secondary data from the literature.

264 The inventory analysis was modelled in SimaPro 8.5.0 (Pré, 2017) and with vers. 3.4 of the
265 Ecoinvent database (Ecoinvent Centre, 2018).

266 The LCI model *attributitional, partitioning*, in terms the presence of the co-product represented by
267 loose powder remaining at the end of the production process, is considered as the most appropriate
268 to best satisfy the assessment requirements (Pini, Neri & Ferrari, 2018). The use of *substitution* in
269 the attributitional data modelling is not considered adequate, as the co-product is not assumed
270 identical, due to additional processes to which it has been subjected, to virgin powder, even if they
271 perform the same function.

272 The allocation is based on energy criterion, in particular non-renewable and renewable energy
273 consumption is taken into account. Energy allocation is preferred because, from a methodological
274 point of view, it is more representative of the studied system, as it takes into account all the stages
275 in the production of stems, from an energy point of view.

276 The weight allocation is declined because it would attribute almost all the damage to the co-
277 product, according to the respective masses involved, neglecting the purpose of the process, that is

278 the production of prostheses. Moreover, this kind of allocation would erroneously equalize the
279 products from an importance point of view. Allocation based on economic value is not performed
280 due to the lack of primary data.

281 **3.5 Impact assessment methodology**

282 The environmental analysis were carried out by the IMPACT 2002+ method, modified in
283 accordance with Pini, Ferrari, Gamberini, Neri and Rimini (2014). Since the IMPACT 2002+
284 method does not taken into account local and indoor emissions, characterization factors for argon
285 and metal emissions were obtained by adopting a preliminary method (Ferrari et al., 2019) in order
286 to calculate indoor and local human effects. These indicators were introduced in the Life Cycle
287 Impact Assessment (LCIA) method.

288 The following were thus added to the above mentioned evaluation in order to consider a wider
289 and more representative scenario of the considered system:

- 290 • New Carcinogens categories were introduced, Carcinogens indoor and Carcinogens
291 local, in particular, new substances are added in the new categories, namely Metals,
292 unspecified indoor and Metals, unspecified local with defined characterization factors
293 calculated with the method mentioned above.

294 In particular, the characterization factor for indoor and local Metals, unspecified result in
295 $1642.011 \text{ kgC}_2\text{H}_3\text{Cl eq./kg}$ and $1255.66 \text{ kgC}_2\text{H}_3\text{Cl eq./kg}$. These values are obtained
296 considering for both factors the damage factor reported in Eco-indicator 99 (EI99) of the
297 analysed substance ($6.969\text{E-}4 \text{ DALY/kg}$), the fate factor and the population density
298 (namely, $3.13\text{E-}5 \text{ m}^2\text{/m}^3$ and $1.17\text{E-}4 \text{ pers/m}^2$, both the fate factor and population
299 density belong to Lindane, the substance that in Annex v. 3 of EI99 has a damage factor
300 near to Metals, unspecified), local and indoor fate factors (namely, $7.39\text{E-}5 \text{ m}^2\text{/m}^3$ and
301 $1.087\text{E-}5 \text{ m}^2\text{/m}^3$, calculated by Eco-indicator 99 formula considering for local emission
302 an emitting area of $4\text{E}8 \text{ m}^2$ and local concentration calculated by Gaussian Plume
303 (Zannetti, 1990), a stationary model used to simulate the air pollutants dispersion into air

304 emitted from a chimney, for indoor emission an emitting area of 25 m²) and local and
305 indoor population density (considering, namely, 100000 inhabitants for the local area
306 and 2 workers in the shed).

307 • A new Non carcinogens category was introduced, Non carcinogens indoor, including
308 Argon with the calculated damage factor. The limit of argon concentration in a working
309 space, considered to be 500 m³, is equal to 0.18 kg/m³ and is calculated considering the
310 increased percentage of argon (up to 10%) in air. Considering a breath rate of 2.5 m³/h
311 and 8 working hours per day, the indoor argon limit of emission was calculated as 3.57
312 kg. Referring to Europe (with a population density of 386 million, Goedkoop &
313 Spriensma, 2001) and considering an average lifetime of 80 years and a 50 year old man
314 exposed to emissions, the damage factor on human health is 2,18E-6 DALY/kg and the
315 resulting characterization factor is 0.78 kgC₂H₃Cl eq./kg.

316

Social category	Social issues	CF	DAF	NF	WF
Industrial product function utility	Medical devices	1			
	Suction systems	1			
	Cooling systems	0.5			
	Heating systems	0.6			
	Mechanical processings	0.9	-1	1	0.001
	Agricultural machines	0.8			
	Electronic devices production	0.6			
	Movement transmission	0.8			
Product performance	Geometry complexity	0.8	-1	$1/(0.8+0.8) =$	0.001
	Biocompatibility	0.8		0.625	

Table 1 Impact/damage categories added in IMPACT 2002+, with each substance, characterization factor (CF), damage assessment factor (DAF), normalization factor (NF) and weighting factor (WF)

317
318

319 The benefits associated with AM compared to traditional manufacturing were also assessed. The
320 aim was to consider the benefits of an AM product that are not considered by LCIA methods. Two
321 social categories were created: Industrial product function utility and Product performance. The first
322 indicator identifies the field of employment of the stem and the second indicator highlights the
323 technical improvement of the stem produced with AM.

324 Both consider several new issues that express, from a subjective point of view, positive aspects,
325 and which were introduced in the method with calculated characterization factors. For each social
326 category, characterization factors (CFs), normalization factors (NFs) and weighting factors (WFs)
327 are reported in Table 1.

328 The CF value ranges from 0 to 1, based on shared values with the stakeholders. DAF was set to a
329 value of -1, in order to consider the benefit provided by AM. The NF of the Industrial product
330 function utility is equal to the maximum value of the characterization factors. On the other hand, for
331 Product Performance, the normalization factor is the reverse of the sum of the characterization
332 factors of its social issues, because the issues can all coexist. WF has a value that is three orders of
333 magnitude lower than the WF of IMPACT 2002+, in order to prevent an excessive influence on the
334 environmental results. Only social issues that are representative of the case study are considered in
335 the AM process, which are Medical devices, Geometry complexity and Biocompatibility. A higher
336 biocompatibility of the stem produced with AM is possible because of the trabecular structure of the

337 surface. This particular geometry, that has been validated from a technical-medical point of view by
 338 the stakeholders (Castagnini et al., 2018), mimics cellular structures of the bone and is not
 339 achievable with other manufacturing processes, and leads to an improved osseointegration of the
 340 prosthesis.

341 3.6 Life cycle inventory

342 The most representative data used in the Life Cycle Inventory of 20 femoral stems production
 343 with the EOS M290 machine with GA powder are reported in Table 2.

345	Input	Value	Unit
346	Materials		
	Flooding argon	3.03	kg
347	Building phase argon	25.94	kg
	Ti ₆ Al ₄ V powder	20.83	kg
348	Energy		
349	Electricity	147.26	kWh
	Transport		
350	Road	6.72	tkm
	Output		
351	Main product		
	20 femoral stems	1.77	kg
352	Co-product		
353	Loose powder	18.99	kg
	Indoor emissions		
354	Metals, unspecified indoor	5.95E-9	kg
	Argon, indoor	1.2E-7	kg
355	Local emissions		
356	Metals, unspecified local	1.9E-3	kg
	Emissions to air		
357	Metals, unspecified	1.71E-2	kg
	Argon	2.89E-4	kg
358	Waste to treatment		
359	Metal recycling	1.9E-2	kg
	Disposal to residual landfill of metals captured by filter	2.08E-2	kg

360 *Table 2 Inventory input data for the AM process of 20 femoral stems with EOS M290*

361 The percentages resulting from the energy allocation between the main product and the co-
 362 product were derived from equations (1) and (2):

$$364 \quad 20 \text{ stems} = \frac{n \text{ Stems} \times (NR \text{ energy}_{1 \text{ stem}} + R \text{ energy}_{1 \text{ stem}})}{(n \text{ Stems} \times (NR \text{ energy}_{1 \text{ stem}} + R \text{ energy}_{1 \text{ stem}})) + (n \text{ kg} \times (NR \text{ energy}_{1 \text{ kg}} + R \text{ energy}_{1 \text{ kg}}))} \times 100 = 58.32\% \quad (1)$$

$$367 \quad \text{Loose powder} = \frac{(n \text{ kg} \times (NR \text{ energy}_{1 \text{ kg}} + R \text{ energy}_{1 \text{ kg}}))}{(n \text{ Stems} \times (NR \text{ energy}_{1 \text{ stem}} + R \text{ energy}_{1 \text{ stem}})) + (n \text{ kg} \times (NR \text{ energy}_{1 \text{ kg}} + R \text{ energy}_{1 \text{ kg}}))} \times 100 = 41.68\% \quad (2)$$

368 where:

- 369 • $NR_{energy_{1stem}}$ is the amount of non-renewable energy, expressed in MJ, required for
370 producing one femoral stem;
- 371 • $R_{energy_{1stem}}$ is the amount of renewable energy, expressed in MJ, required for producing
372 one femoral stem;
- 373 • $NR_{energy_{1kg}}$ is the amount of non-renewable energy, expressed in MJ, required for
374 producing 1 kg of metallic powder;
- 375 • $R_{energy_{1kg}}$ is the amount of renewable energy, expressed in MJ, required for producing
376 1 kg of metallic powder;
- 377 • n_{Stems} are the number of stems produced in one job;
- 378 • n_{kg} are the number of kilograms of loose powder remaining at the end of the job.

379 **4 Results: Impact assessment**

380 An environmental analysis of the life cycle of one femoral stem produced with GA powder was
381 performed. The single score damage was equal to $2.36E-2 Pt^1$ for GA powder usage. The results of
382 the analysis at the mid-point level for GA powder employment are reported in Table 3.

383 Figure S-1 highlights that the most significant contribution to the total damage is due to the
384 Respiratory inorganics impact category (36.34%), which, in turn, is primarily affected by
385 Particulates, $<2.5 \mu m$ (49.94%) due to the production phase (82.72% on total damage of the specific
386 category), in particular for electric energy consumption. Subsequently, the second largest
387 contribution to the total damage is generated by the Non-renewable energy impact category
388 (24.78%), mainly due to Coal, hard (29.42% on total damage of the specific category). This is used
389 in the productive process (78.74% on total damage of the specific substance), especially for energy
390 consumption in primary titanium production, used for the alloy production. In terms of Global
391 warming (24.10%) the main damage is due by Carbon, dioxide fossil (93.02% on total damage of
392 the specific category), especially in the production (68.2% on total damage of the specific

¹ Pt is the abbreviation of “points”.

393 substance) and use phases (31.77% on total damage of the specific substance), in particular for the
394 incineration of hazardous surgery waste.

395 The human health is affected by the release of Hydrocarbons, aromatic (80.71%) which
396 influence Carcinogens (outdoor environment, 5.7% on total damage of the specific category),
397 especially in the use phase (85.96% on total damage of the specific substance) for the production of
398 surgery towels in PET.

399 The other impact categories provide less than 5% of the total damage.

Impact category	Unit	Total	Production phase	Use phase	End of life
Carcinogens	kg C2H3Cl eq	3.41E+00	9.46E-01	2.46E+00	5.64E-04
Non-carcinogens	kg C2H3Cl eq	1.14E+00	8.04E-01	3.33E-01	5.37E-04
Respiratory inorganics	kg PM2.5 eq	8.70E-02	6.92E-02	1.78E-02	2.92E-05
Ionizing radiation	Bq C-14 eq	9.81E+02	6.37E+02	3.43E+02	2.69E-01
Ozone layer depletion	kg CFC-11 eq	5.14E-06	3.75E-06	1.38E-06	2.02E-09
Respiratory organics	kg C2H4 eq	1.69E-02	1.16E-02	5.32E-03	8.43E-06
Aquatic ecotoxicity	kg TEG water	5.55E+03	3.15E+03	2.40E+03	2.61E+00
Terrestrial ecotoxicity	kg TEG soil	9.94E+02	6.52E+02	3.41E+02	6.65E-01
Terrestrial acid/nutri	kg SO2 eq	8.19E-01	5.99E-01	2.20E-01	3.27E-04
Land occupation	m2org.arable	5.87E+00	4.31E+00	1.56E+00	1.17E-03
Aquatic acidification	kg SO2 eq	2.51E-01	1.83E-01	6.80E-02	9.68E-05
Aquatic eutrophication	kg PO4 P-lim	1.56E-02	1.11E-02	4.55E-03	1.68E-05
Global warming	kg CO2 eq	5.64E+01	3.88E+01	1.76E+01	1.75E-02
Non-renewable energy	MJ primary	8.90E+02	5.74E+02	3.16E+02	2.82E-01
Mineral extraction	MJ surplus	8.93E+01	6.39E+01	2.53E+01	1.39E-01
Energia rinnovabile	MJ	9.89E+01	6.93E+01	2.95E+01	5.56E-02
Non-carcinogens, indoor	kg C2H3Cl eq	1.69E-05	1.69E-05	0.00E+00	0.00E+00
Respiratory organics, indoor	kg C2H4 eq	0.00E+00	0.00E+00	0.00E+00	0.00E+00
Respiratory inorganics, indoor	kg PM2.5 eq	0.00E+00	0.00E+00	0.00E+00	0.00E+00

Table 3 Characterized LCIA results at mid-point level of 1 femoral stem life cycle with GA powder

401 The endpoint analysis highlights (Table 4) that the phases of the life cycle with the highest
402 environmental burdens are the production (69.32%) and the use phase (30.65%), followed by end of
403 life (0.035%). Moreover, 44.07% of the total damage affects Human Health, 27.26% affects
404 Resources, 24.10% affects Climate Change, 4.75% the Ecosystem Quality, 3.22E-2% the Human
405 health, local and for 3.76E-5% the Human health, indoor. The categories Product performance and
406 Industrial product function utility provide an advantage of -9.85E-2% and -1.23E-1%, respectively.

407

Damage category	Unit	Total	Production phase	Use phase	End of life
Total	Pt	2.36E-02	1.64E-02	7.25E-03	8.37E-06
Human health	Pt	1.04E-02	7.54E-03	2.88E-03	3.32E-06
Resources	Pt	6.45E-03	4.20E-03	2.24E-03	2.77E-06
Climate change	Pt	5.70E-03	3.92E-03	1.78E-03	1.76E-06
Ecosystem quality	Pt	1.12E-03	7.77E-04	3.47E-04	5.11E-07
Human health, local	Pt	7.61E-06	7.61E-06	0.00E+00	0.00E+00
Human health, indoor	Pt	8.89E-09	8.89E-09	0.00E+00	0.00E+00
Product performance	Pt	-2.33E-05	-2.33E-05	0.00E+00	0.00E+00
Industrial product function utility	Pt	-2.91E-05	-2.91E-05	0.00E+00	0.00E+00

Table 4 LCIA results at end-point level of 1 femoral stem life cycle with GA powder

408

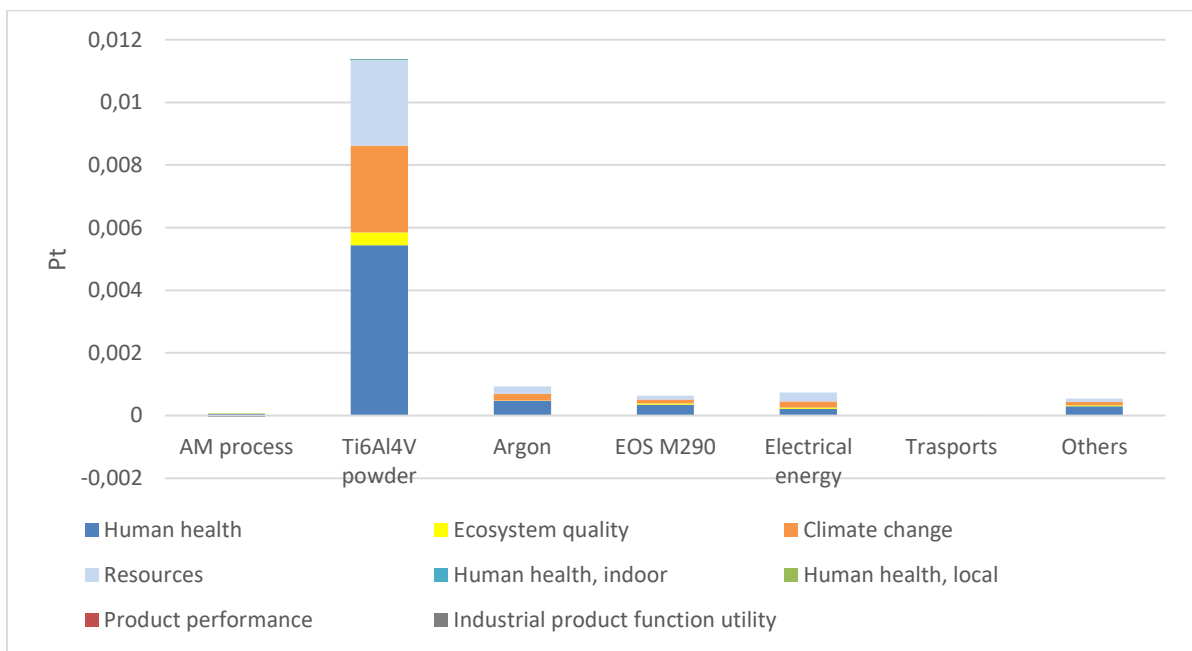


Figure 3 LCIA results at end-point level of 1 femoral stem AM process with GA powder. Underlying data used to create this figure can be found in supporting information S-2 on the Web

409
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411

412 End-point analysis of one femoral stem production phase is 1.64E-2 Pt, where the AM process
413 (86.79%) has the highest environmental load, and post-production treatments (6.46%) and other
414 processes (6.73%) contribute to a lesser extent.

415 The analysis of the end-point analysis of the AM process (Figure 3) shows that the total damage
416 (1.42E-2 Pt) is: 79.88% for Ti₆Al₄V powder production with GA, 6.55% for argon consumption and
417 5.18% for electrical energy consumption.

418 The damage assessment analysis shows that damage to the Human health accounts for 47.95% of
419 the total damage, in particular with the substance Particulates, <2.5 μm (air) (49.08%, divided into
420 82.54% for powder production and 7.9% for argon consumption).

421 The Resources category provides 24.61% of the total damage, mainly for the substance Coal,
422 hard (35.84%, due especially to the energy production for primary titanium used in alloy powder).
423 The damage to Climate change (24%) is caused almost entirely by the substance Carbon dioxide,
424 fossil (93.51%), 81% emitted for during gas atomization and 6.39% for argon consumption.

425 Aluminium in air affects the category Ecosystem quality (3.75% of the total damage) and is
426 linked to the blasting process for hard coal extraction, used to produce energy, necessary for
427 Ti₆Al₄V bar production process.

428 Human health, local accounts for 5.24E-2% due almost entirely (99.99%) to Metal, unspecified,
429 local emitted during parts extraction and machine cleaning.

430 The Human health, indoor category contributes to the total damage with 6.24E-5% due, mainly,
431 to indoor argon emissions during exhausted argon treatment and Ti₆Al₄V powder production, and
432 then to indoor metal emissions occurring while treating exhausted argon, Ti₆Al₄V powder
433 production and femoral stem production processes.

434 Finally, Industrial product function utility and Product performance provide environmental
435 advantages, of -2E-1% and -1.64E-1% respectively.

436 **4.1.1 Comparison of atomization processings**

437 As Ti₆Al₄V powder production causes most of the total damage, a further atomization
438 technology, PA, was investigated in order to assess the most sustainable one. The comparison
439 between 1 kg of Ti₆Al₄V powder produced with GA and PA highlights the higher damage
440 (+12.31%) of PA (2.1E-2 Pt) compared to GA (1.87E-2 Pt). In fact, Ti₆Al₄V powder production
441 with PA provides a higher contribution to the total damage compared to GA because of the greater
442 use of argon (2.56 kg of argon to produce 1 kg of powder) compared to GA (0.007 kg for 1 kg of
443 powder), as EOS reported in direct interview (2017), and because of the lower atomization
444 productivity of this technology (80 kg of powder produced in 16 hours) compared to GA
445 productivity (500 kg in the same cycle) (EOS, 2017).

446 The damage category with the highest increase is Human health, indoor) which is two orders of
447 magnitude higher, due to a higher amount of argon sent to treatment, followed by Resources
448 (+18.38%), Climate change (+11.15%), Human health (+10.6%) and Ecosystem quality (+1.46%).
449 Moreover, if higher argon consumptions for GA are considered (0.5 kg argon and 2 kg argon for 1
450 kg of powder), the comparison between the two production technologies provides as result higher
451 damage for PA (namely, +10.8% and +6.3%).

452 Therefore, as compared with PA, GA, was shown to be the most sustainable option, it was
453 chosen for further investigations.

454 **4.1.2 Comparison of femoral stem production lines (traditional versus AM)**

455 A comparison between femoral stem production with GA powder and traditional manufacturing
456 is reported below.

457 The production phase of 1 femoral stem with traditional manufacturing has a higher impact
458 ($2.03E-2$ Pt), +24.08% compared to the AM process, caused by the higher rate of metal scraps (15.4
459 kg) that are sent for recycling. Waste powder resulting at the end of the AM process (0.019 kg) and
460 metal scrap resulting from stem's head machining (0.117 kg) are sent to recycling, too.

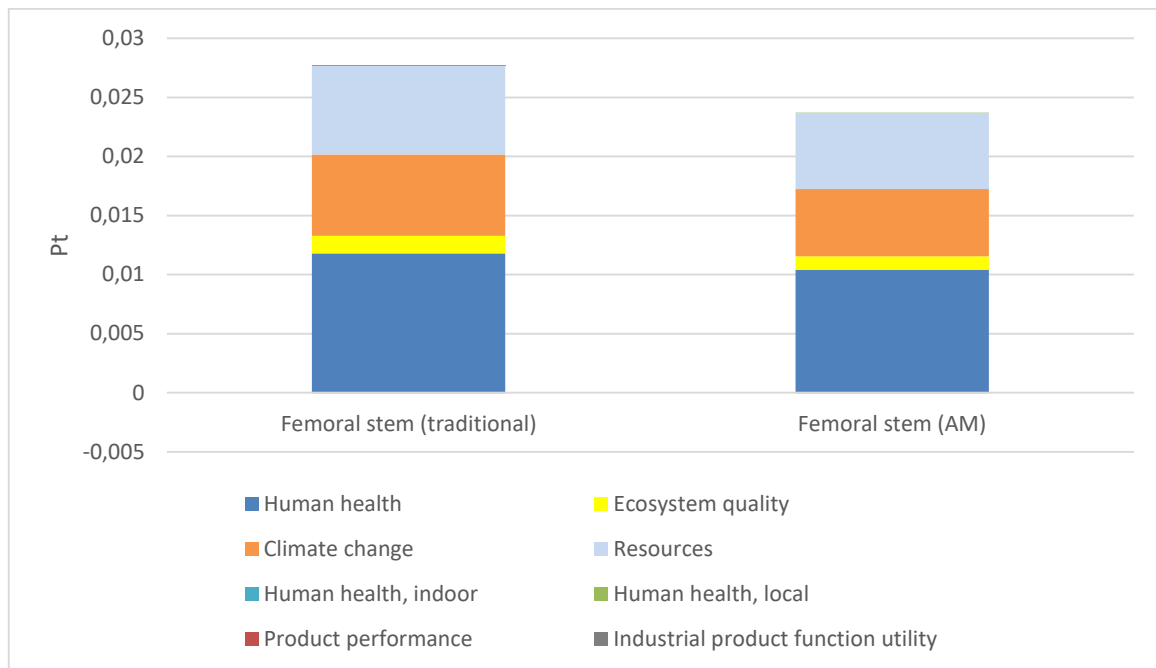
461 The co-product of AM (about 19 kg of loose powder), in fact, provides a damage reduction to the
462 function. Traditional manufactured parts benefit only from the advantage of the Industrial product
463 function utility. In particular, the indicator Product performance adds to the production of the AM
464 stem an advantage (-0,14%) precluded to traditional technology thanks to the novel geometry
465 imprinted by AM, while the benefit derived from Industrial product function utility, considered for
466 traditional production as well, is more limited in the case of additive production (-0.18%) compared
467 to subtractive production (-0.25%) due to allocation of the co-product. As a consequence of the
468 changed geometry, the stem produced with AM, 82.8 g, is lighter (-21%) compared to the one
469 produced with traditional manufacturing, 104.6 g.

470 A comparison between the complete life cycle damage of the part produced with traditional
471 manufacturing and AM (with GA powder) is provided (Figure 4). $2.76E-2$ Pt is the total damage of

472 the life cycle of one femoral stem produced with traditional manufacturing which exceeds AM by
473 16.94% of total damage (2.36E-2 Pt).

474 The traditional production of 1 femoral stem equals to the share of 73.6% of overall life cycle
475 impact. The use and end of life phases of the traditional stems were found to be equal to the AM
476 stems.

477



478
479
480

Figure 4 Environmental comparison between life cycle of 1 femoral stem produced with traditional manufacturing and with AM. Underlying data used to create this figure can be found in supporting information S-3 on the Web

481 4.1.3 Sensitivity analysis

482 Let us now make a final comparison between the life cycle of one stem made with traditional
483 manufacturing and the life cycle of one reference stem made with additive manufacturing.

484 The reference femoral stem is defined as the stem with the average impact from among 160
485 stems produced in eight jobs.

486 Researchers estimate that loose powder can be reused eight times (Faludi, Baumers, Maskery &
487 Hague, 2016), thus eight jobs, each producing 20 stems, are considered. The first job employs
488 20.83 kg of virgin powder, however the subsequent jobs use the remaining powder from the
489 previous one, adding a small quantity of virgin powder to compensate for the powder lost with
490 waste and printed parts.

491 Damage, in fact, is not constant from one job to another, as the amount of virgin powder
492 introduced into the machine changes and the loose powder coproduct retrieved in each job has a
493 variable impact. In particular, damage decreases until the 7th job, but increases at the 8th job, due to
494 the higher amount of metal powder waste that could not be reused and is sent to recycling.

495 The results of the analysis (Figure S-4) shows that the stem produced traditionally has higher
496 damage compared to the reference stem made with AM (1.81E-2 Pt) of 52.38% which this is due
497 mainly to the reduction of damage associated with the virgin powder introduced in the machine.

498 The LCI modelling of the eight processes (i.e. the eight jobs) is performed once again with
499 attributional, partitioning with energy allocation because loose powder is subjected to further
500 processings, job after job, that could not be adequately expressed with other allocation criterions.

501 **5 Conclusions**

502 In this work, the environmental sustainability of orthopaedic devices with AM was evaluated
503 with the life cycle assessment methodology.

504 A cradle to grave LCA was applied for one femoral stem produced using AM and GA powder
505 and, as a result, the highest environmental burden was found to be the production phase, followed
506 by the use and end of life phases.

507 The analysis of results highlighted that the main environmental load in the production phase is
508 due to titanium alloy powder production. The same influence of titanium alloy powder production
509 on total damage was found by Serres et al. (2011) and Peng et al. (2017). In this study two different
510 titanium alloy powder production technologies (GA and PA) were therefore compared in order to
511 highlight the most appropriate option for minimizing environmental loads and protecting human
512 health.

513 The analysis of results illustrates that the most sustainable choice for powder production is GA.

514 An analysis of the benefits derived from the AM process compared to traditional manufacturing
515 was also conducted, taking into account socially positive aspects (never considered before in E-
516 LCA studies on additive manufacturing) related to the part produced with AM and concerning the

517 increased biocompatibility and more complex geometry of prostheses. In particular, the indicator
518 Product performance adds to the life cycle of the AM product an advantage (-0,098%) precluded to
519 traditional technology, while the benefit derived from Industrial product function utility, considered
520 for traditional production as well, is more limited in the case of additive production (-0,12%)
521 compared to subtractive production (-0,18%) due to allocation of the co-product.

522 These aspects provide an insight into the high level of innovation introduced by this technology,
523 which is aimed at meeting customer's needs.

524 Local and indoor emissions were included in the study and their incidence on total damage
525 (namely 3.22E-2% and 3,76E-5%) was found to be very limited, thanks to the high filtration
526 efficiency of HEPA filters and filter mask category P3.

527 The comparison showed that the AM process (in the GA powder usage hypothesis) is the most
528 sustainable option. This is due to the presence of the co-product, represented by loose powder
529 recovered at the end of the productive process, which reduces the damage to the function, choosing
530 energy input as allocation criterion.

531 A further damage reduction compared to the traditional stem was highlighted when a reference
532 stem, obtained by averaging the impact of 160 stems produced in 8 jobs, is considered. This final
533 analysis highlights the extent of the benefits of additive manufacturing represented by the
534 possibility of reusing loose powder, which is very difficult to investigate without considering all the
535 jobs in which loose powder is employed.

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662

663 **Supporting information**

664 Supporting information 1: This supporting information provides data about the weighted results by
665 impact categories of 1 femoral stem life cycle produced with AM and with GA powder. Underlying
666 data used to create this figure can be found in supporting information S-5 on the Web

667 Supporting information 2: This supporting information provides data plotted in figure 3 of the main
668 text.

669 Supporting information 3: This supporting information provides the data used in figure 4 of the
670 main text.

671 Supporting information 4: This supporting information provides data about the comparison between
672 endpoint results of 1-cycle-approach (comparison between one traditional stem and one AM stem,
673 top histogram) and 8-jobs-approach (comparison between one traditional stem and one reference
674 stem (AM), bottom histogram). Underlying data used to create this figure can be found in
675 supporting information S-6 (top histogram) and S-3 (bottom histogram)

676 Supporting information 5: This supporting information provides data plotted in figure S-1 of the
677 Supporting information.

678 Supporting information 6: This supporting information provides data about the underlying data used
679 for the comparison between results of 1-cycle-approach (top histogram of figure S-4)

680 **Figure Legends**

681 Figure 1: System boundaries of femoral stem life cycle with AM

682 Figure 2: System boundaries of femoral stems life cycle with traditional manufacturing

683 Figure 3: LCIA results at end-point level of 1 femoral stem AM process with GA powder.

684 Underlying data used to create this figure can be found in supporting information S-2 on the Web

685 Figure 4: Environmental comparison between life cycle of 1 femoral stem produced with traditional

686 manufacturing and with AM. Underlying data used to create this figure can be found in supporting

687 information S-3 on the Web