Spinal implants
(Interbody cage, interspinous process spacer, spacer, lumbosacral support implant)

Summary

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Project management Team
This report was produced by Albane MAINGUY, project manager, Medical Devices Assessment Department, tel.: 01 55 93 37 35, e-mail: a.mainguy@has-sante.fr

The following also worked on this dossier:
- for the analysis and rating of clinical trials and meta-analyses, Estelle PIOTTO-PEYLAN, project manager, Medical Devices Assessment Department, tel.: 01 55 93 37 72, e-mail: e.piotto@has-sante.fr
- for the analysis of hospital activity linked to the implantation of spinal implants and for estimating the target population, Emmanuelle SCHAPIRO-DUFORT, project manager, Medical Devices Assessment Department, tel.: 01 55 93 37 76, e-mail: e.schapiro@has-sante.fr

The literature research and document management were carried out by Sophie DESPEYROUX (researcher, Documentation and Public Information Department, tel.: 01 55 93 73 54, e-mail: s.despeyroux@has-sante.fr) and Sylvie LASCOLS (assistant researcher, Documentation and Public Information Department, tel: 01 53 93 73 29, e-mail: s.lascols@has-sante.fr).

The organisation of meetings and secretarial work were done by Yakaré TOUNKARA (tel.: 01 55 93 37 45, e-mail: y.tounkara@has-sante.fr).

Managers:

Catherine DENIS (head of the Medical Devices Assessment Department, tel.: 01 55 93 37 40, e-mail: c.denis@has-sante.fr).

Corinne COLLIGNON (deputy head of the Medical Devices Assessment Department, tel.: 01 55 93 37 44, e-mail: c.collignon@has-sante.fr).

Frédérique PAGÈS (head of the Documentation and Public Information Department, tel.: 01 55 93 73 23, e-mail: f.pages@has-sante.fr).
Composition of the working group

The working group was made up of the following professionals:

- Dr Mohamed ALLAOUI, neurosurgeon, Roger Salengro Hospital, LILLE (59)
- Dr Thierry BAZIN, rheumatologist, Louis Dupic Medical Centre, VÉNISSIEUX (69)
- Dr Luc CHADAN, neurosurgeon in private practice, COMC de Dracy-le-Fort, DRACY-LE-FORT (71)
- Dr Patrick CHASTANET, radiologist, Roger Salengro Hospital, LILLE (59)
- Dr Mathieu DE SEZE, physical medicine and rehabilitation, Pellegrin Hospital Group, BORDEAUX (33)
- Dr Alexis FAURE, neurosurgeon, Parc de Cholet Polyclinic, CHOLET (49)
- Dr Stéphane GOUTAGNY, neurosurgeon, Beaujon Hospital, CLICHY (92)
- Prof. Olivier HAUGER, radiologist, Bordeaux University Hospital, BORDEAUX (33)
- Prof. Bernard IRTHUM, neurosurgeon, Gabriel Montpied Hospital, CLERMONT-FERRAND (63)
- Dr Mohamed Amine LAHLOU, neurosurgeon, Strasbourg University Hospital, STRASBOURG (67)
- Prof. Serge NAZARIAN, orthopaedic surgeon, Hospital of the Conception, MARSEILLE (13)
- Dr Remi PREBET, orthopaedic surgeon, Saint-Léonard Clinic, TRÉLAZÉ (49)
- Prof. Richard-Alexandre ROCHWERGER, member of CNEDIMTS, orthopaedic surgeon, Hospital of the Conception, MARSEILLE (13)
- Prof. Nicolas SANS, radiologist, Toulouse University Hospital, TOULOUSE (31)
- Prof. Jean-Rodolphe VIGNES, neurosurgeon, Bordeaux University Hospital, BORDEAUX (33)

The members of the working group were appointed by the CNEDIMTS board from among the experts proposed by the relevant associations or learned societies, experts who responded to an appeal for candidates and experts known to HAS.

In accordance with Decree No. 2004-1139 of 26 October 2004 (Art. R. 161-84 to R. 161-86 of the Social Security Code), all members of the working group completed a declaration of interests, mentioning direct or indirect links with any company or body involved in the field covered by the missions of HAS. These declarations of interests were published on the HAS website.

The analysis of the declarations of interests was carried out in accordance with the criteria of the HAS “Guide to declarations of interest and the management of conflicts of interests” (adopted by
the HAS Board on 3 March 2010). A table summarising the declared interests was examined by the CNEDiMTS board which decided on the final composition of the working group. The interests declared by the experts selected were all regarded as “not major” by the CNEDiMTS board.

The summary table of declared interests was published and, if necessary, updated on the basis of the experts’ updated declarations of interests at the start of each meeting of the working group and on presentation of the working group’s position at CNEDIMTS.

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http://www.has-sante.fr/portail/upload/docs/application/pdf/guide_dpi.pdf
Summary

Background

Spinal implants are used in diseases such as disc herniation, degenerative diseases and post-traumatic instabilities. They are implanted following two surgical procedures which can be combined: arthrodesis (osteosynthesis, whether or not combined with a bone graft) and osteosynthesis alone. Osteosynthesis consists in keeping the fragments of a bone together by means of implants. The equipment used generally consists of internal fixation. The aim of arthrodesis is to permanently lock one or more intervertebral joints in the spinal column by fusing the bone in two or more vertebrae. Fusion is quickest when a graft is used in combination with osteosynthesis. The combination of arthrodesis with osteosynthesis makes it possible to give immediate stability to an unstable spine or one which has been destabilised by an operation, to correct a spinal deformity or intervertebral disc displacement, and to improve the bone fusion rate by reducing the risk of pseudarthrosis.

Whatever procedure is used, there are two possible routes of approach (anterior and posterior) and they can either be combined or used alone, depending on the type of deformation, its rigidity and its severity. These two routes use designs of device adapted to the patient’s anatomy.

This revision on spinal implants was made in the context of an opinion which appeared in the Official Journal on 8 September 2011, and concerns spinal implants belonging to four categories in the nomenclature, defined as follows:
  - interspinous process spacer;
  - spacer;
  - lumbosacral support implant;
  - interbody cage.

Objectives – Working method

The objectives of this work were to reassess spinal implants so as to:
  - determine the indications for spinal implants;
  - assess their actual benefit per indication;
  - define their place in therapeutic strategy;
  - characterise the technical specifications which determine the actual benefit, so as to avoid classification mistakes and to clarify which devices are covered by the current generic description;
  - propose an updated nomenclature based on the form and composition of devices;
  - estimate their target population;
  - define the expectations of CNEDiMTS regarding clinical trials needed for inclusion under the brand name on the List of products and services qualifying for reimbursement (LPPR);
  - define the conditions of use and prescription for inclusion of the products on the LPPR.

The working method is based on a systematic review of the literature and an analysis of the dossiers submitted by manufacturers, and draws on the expertise of healthcare professionals meeting in the multidisciplinary working group dedicated to the subject.
Assessment – Analysis of the data

The assessment covered the following assessment criteria: pain, patient satisfaction, quality of life, the Oswestry Disability Index (ODI score), the fusion rate, the length of the operation, blood loss, complications and the reoperation rate.

The literature data show that spinal implants are used in several diseases:
- cervical degenerative diseases;
- lumbar degenerative diseases, including chronic low back pain.
In other indications such as fractures, tumours and specifically in cervical spondylosis, the literature data are limited, or even nonexistent.
Studies confirm the benefit of techniques using interbody cages and reconstruction implants after corporectomy, but do not allow an assessment of these implants alone (particularly the cages, which are often combined with osteosynthesis).
The data are conflicting as regards the benefit of interspinous process implant.
There are no specific data on sacral support implants used in addition to longitudinal osteosynthesis or on spacer.
There are no clinical data that can be used to claim the benefit of one implant over another, and there are very few descriptions of the technical specifications of the implants.

Working group opinion

In the absence of literature with a good level of evidence and or good grades of recommendations, the working group’s proposals are based mainly on the members’ clinical practice.

Since no precise definition of spinal implants is available in the literature, the group defined each of these devices by stating their technical specifications, and described the indications in which these implants are used. The group also specified the methods of use, particularly the need for additional osteosynthesis when implanting a cage or a reconstructive vertebral body implant and the limitation to one reconstructive vertebral body implant per level treated if several levels are treated.

The working group’s main proposals on the nomenclature concerned:
- the distinction of interbody cages and reconstruction implants after corporectomy;
- for cages and reconstructive vertebral body implants, the creation of generic descriptions according to their anatomical level (cervical and thoracolumbar), the presence or otherwise of a bone substitute and an integrated fixing system;
- the suppression of generic descriptions concerning interspinous process spacer because of the disparity of their designs and their technical specifications and the proposal of registration under the brand name;
- the suppression of generic descriptions concerning spacer because of the heterogeneity of these devices, the inability to define and describe the indications and common, minimal technical specifications and the proposal of registration under the brand name;
- the inclusion of sacral support implants with longitudinal fusion implants, since they cannot be assessed separately from osteosynthesis implants.

General conclusion of the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS)

The CNEDiMTS accepted most of the working group’s proposals, adding a few precisions about the benefit of reconstructive vertebral body implants.
In fact, after corporectomy the spine is unstable, and reconstruction implants after corporectomy need an effective anchorage system which is provided by a decompression system in the implant.
Overall, this assessment has confirmed the benefit of interbody cages, and the distinction of reconstruction implant after corporectomy. In addition, it did not produce any evidence of the benefit of interspinous process spacer or spacer.

Two main categories of spinal implants are identified for inclusion under a generic description:

1. interbody cages
2. reconstruction implants after corporectomy

The committee recommends, for these two types of implants, the creation of eight generic descriptions according to the level treated (cervical and thoracolumbar) and according to whether or not there is a bone substitute and an integrated fixing system. For a given indication, the CNEDIMTS ruled that there is no added clinical value (ACV V) of one line over another.

The committee recommends, for the categories “interspinous process spacer” and “spacer”, deletion of these generic descriptions and inclusion by brand name.

Finally, for the category “lumbosacral support implants”, the committee recommends the reinclusion of the generic description for longitudinal reconstructive implants.

The CNEDIMTS defined the criteria for assessing devices under their brand name if they do not meet the technical specifications of the proposed generic descriptions.

For cages and reconstructive vertebral body implants, manufacturers must prove efficacy by means of a randomised controlled trial versus well-managed medical treatment or versus surgery (conventional arthrodesis with an autologous graft and osteosynthesis) with a follow-up period of not less than 24 months. The recommended outcomes are:

- clinical endpoint: the pain assessed on the VAS (visual analogue scale) and radicular pain, quality of life (SF-12 or SF-36 quality of life questionnaire), the neck disability index (NDI) or the lumbar disability index (LDI), functional endpoint: the walking distance (according to the disease treated); the primary endpoint will be selected from among these clinical outcomes;
- radiological endpoint (standard X-ray, CT scan or MRI showing the discopathy).

For interspinous process spacer and spacer, manufacturers must prove efficacy by means of a randomised controlled trial versus well-managed medical treatment or versus surgery, in the indication claimed (for interspinous process spacer, the identified indication is dynamic stenosis or discopathy). The CNEDIMTS recommends follow-up for 24 months with interim results at 6 months. The recommended outcomes are:

- clinical endpoint: lumbar and radicular pain assessed on the VAS (visual analogue scale), quality of life (quality of life questionnaire SF12 or SF36), functional endpoint: the JOA (Japan Orthopaedic Association), the walking distance;
- radiological endpoint (standard X-ray, CT scan or MRI, since a dynamic X-ray could be a contraindication to the insertion of an interspinous process implant, bone computed tomography). These outcomes should be adapted according to the disease treated. According to the indication, other outcomes can be considered and the period of follow-up adapted (particularly in oncology). In all cases, the outcomes used must be validated.
## List of abbreviations

ACD | Anterior cervical discectomy without fusion  
ACDF | Anterior cervical discectomy and fusion  
AFIDEO | Association of European manufacturers, importer and distributors of orthopaedic and traumatiological implants  
AHCPR | Agency for Health Care Policy and Research  
ALIF | Anterior lumbar interbody fusion  
ANSM | National Medicines and Health Products Safety Agency (formerly Afssaps)  
Afssaps | French Health Products Safety Agency  
ACV | Added clinical value  
CCAM | Joint classification of medical procedures  
CEPP | Committee for the assessment of products and services  
CEPS | Committee for the Pricing of Healthcare Products  
CF | Circumferential fusion  
CNAMTS | National Salaried Workers’ Health Insurance Fund  
CNEDIMTS | National Committee for the Evaluation of Medical Devices and Health Technologies  
DGOS | Directorate General for the Provision of Healthcare  
DGS | Directorate-General for Health  
DSS | Social Security Directorate  
RCT | Randomised controlled trial  
VAS | Visual analogue scale  
HAS | Haute Autorité de Santé  
CI | Confidence interval  
MRI | Magnetic resonance imaging  
JOA | Japanese Orthopaedic Association  
LPPR | List of products and services qualifying for reimbursement  
MCS | SF-36 mental composite score  
MD | Median difference  
NASS | North American Spine Society  
NDI | Neck Disability Index  
NGAP | General Nomenclature of Medical Procedures  
NICE | National Institute for Health and Clinical Excellence  
NR | Not known  
NS | Non-significant  
OCS | Oxford Claudication Score  
ODI | Oswestry Disability Index  
OR | Odds ratio  
PCS | SF-36 physical composite score  
PEEK | Polyetheretherketone  
PEKEKK | Polyetherketoneetherketoneketone  
PLDLLA | Poly-L-lactide-co-D,L-lactide  
PLF | Posterolateral fusion
PLIF  Posterior lumbar interbody fusion
PMSI  Programme for clinical information systems
RPC  Clinical practice guideline
RR  Relative risk
RSA  Summary of anonymised withdrawals
RSI  Health and retirement scheme for independent workers
SA  Expected clinical value
SD  Standard deviation
SFNC  French Society of Neurosurgery
SFR  French Society of Radiology
SIE  Interspinous system
SMD  Standard median difference
SNATIH  National System of Information on Hospital Admissions
SNITEM  National union of the medical technology industry
SOFCOT  French Society of Orthopaedic and Trauma Surgery
SSTF  Short segment transpedicular fixation
SR  Clinical value
SWT  Shuttle walk test
TENS  Transcutaneous electrical nerve stimulation
TDR  Total disc replacement
TLIF  Transforaminal lumbar interbody fusion
XLIF  eXtreme lateral interbody fusion
ZCQ  Zurich claudication questionnaire