SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

BDyn

REVISION		Date	Revised by
Issue 1	Creation of this document – Conformity with the regulation 2017/745 (UE)	23/09/2022	H.MIERSMAN
Issue 2	Update according to SGS review for MDR certification	19/04/2024	H.MIERSMAN
Issue 3	Update according to SGS review for MDR certification	19/07/2024	H.MIERSMAN

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Abbreviations list

CEP	Clinical evaluation report
EU	European union
IFU	Instructions for use
MDR	Medical device regulation
PMCF	Post market clinical follow up
PMS	Post market surveillance
PSUR	Periodic safety update report
SRN	Single registration number
SSCP	Summary of safety and clinical performance
TD	Technical Documentation
UDI	Unique device identification

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INTRODUCTION

This Summary of Safety and Clinical Performance (SSCP) is produced in alignment with the requirements of COUSIN BIOTECH's Clinical Evaluation Plan (TF06_CEP_ISSUE-3_2024-07-18) and REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, referencing the MDCG 2019 – 9 - Summary of safety and clinical performance: A guide for manufacturers and notified bodies.

This SSCP is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

This SSCP is an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information. The SSCP for Sterile Spinal Dynamic Posterior Stabilization Devices composed of BDyn includes both information intended for healthcare professionals (Section A) as well as for the patient (Section B).
The SSCP for BDyn is based on the following documentation pertaining to the BDYN device

- Clinical Evaluation Report (CER)
- Post-Marketing Surveillance (PMS) plan and regular reports
- Post-Marketing Clinical Follow-up (PMCF) plan and regular reports
- Design verification/validation reports
- If appropriate, the IFU

The SSCP shall be reviewed on an annual basis and updated if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete after implementation of the PMCF reports and of the Periodic Safety Update Report (PSUR). Any pertinent modification in the documentation pertaining to BDyn shall be implemented in all sections of the SSCP if needed.

The SSCP of BDyn must contain all the information detailed in this template. However, the manufacturer may add further information from the Technical Documentation (TD) of the device to enhance the comprehension of the mandatory information if it does not affect the readability of the SSCP and if it excludes any element of a promotional nature.
For the sake of objectivity and impartiality to the patients, information in the SSCP shall adequately summarize both favorable and unfavorable data.
The IFU shall provide all relevant information needed to directly access the SSCP in Eudamed. The IFU shall be updated regularly on this database. The following applies to the IFU:

- It shall state that the SSCP is available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI.
- It should provide the URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed
- It should state the value of the Basic UDI-DI. Alternatively, another metadata can be stated provided it can be used to unambiguously search and find the intended SSCP in Eudamed.

The MDR requires that the SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient. The SSCP should therefore be translated into the languages accepted in the Member States where the device is sold/envisaged to be sold. By analogy, this is also a requirement for an IFU.

SECTION 1: SSCP FOR USERS/HEALTHCARE PROFESSIONALS

The following information is intended for users/healthcare professionals. A summary intended for patients can be found in Section B.

1. IDENTIFICATION OF THE DEVICE AND GENERAL INFORMATION

The sterile spinal dynamic posterior stabilization device is intended to restore the stabilization of the non-cervical segment of the spine by preserving the anatomical lordosis and the deadening of the intervertebral joint. It is composed of the BDyn spinal shock absorber fixed on the vertebrae thanks to the dedicated screws.

1.1. DEVICE TRADE NAME(S)

The device under evaluation is marketed under the following trade name : BDyn.

1.2. MANUFACTURER'S NAME AND ADDRESS

COUSIN BIOTECH
Allée des Roses
59117 Wervicq-Sud
FRANCE

1.3. MANUFACTURER'S SRN

The Single Registration Number (SRN) of the manufacturer is FR-MF-000001179.

1.4. BASIC UDI-DI

The Basic UDI-DI of BDyn is : 375018557BDYNSPINALIMPM4

1.5. MEDICAL DEVICE NOMENCLATURE DESCRIPTION / TEXT

Not applicable yet.

1.6. CLASS OF DEVICE

CATEGORY	CLASSIFICATION
Duration	Permanent/long term
Invasive device	Yes
Body contact	Implant
Biological effect	No
Usage	Single use
Sterile	Yes (ETO)*
Active medical device	No
Software	No
Medicinal substance	No medicinal derived from animal tissue or human blood is incorporated in the devices**
Biological material	No material derived from animal tissue or human blood is incorporated in the devices
Radioactive device	The devices are not radioactive

* The implants are designed for long-term implantation. They are sterilized by ethylene oxide and designed for single-use.

** The implanted materials of BDyn Titanium alloy Ti6Al4V ELI, Polydimethyl siloxane (PDMS) MED 4770 unrestricted and Polycarbonate urethane (PCU) Bionate® II 80A do not contain products derived from human or animal origin.

All Sterile Spinal Dynamic Posterior Stabilization Devices included in this EC technical file are in Class III according to the Annex VIII, Chapter III, Rule 8 (§5.4) of the classification criteria of the Regulation (EU) No 2017/745.

1.7. YEAR WHEN THE FIRST CERTIFICATE WAS ISSUED COVERING THE DEVICE

The products concerned by this EC marking file have been initially developed, EC marked and then commercialized under the name “BDyn” for the spinal shock absorber and “BFus” for the polyaxial pedicle screws and rigid rods by the company BIOSPINE Implants (S14 Implants) from November 2008 to January 2017. Since November 2008, about 5000 BDyn spinal shock absorbers and more than 28 000 polyaxial pedicle screws with plugs and rigid rods have been sold worldwide. Then, the 02nd of February 2017, the company COUSIN BIOTECH has bought the BDyn and BFus devices to relaunch them on the market when the new EC marking will be effective.

1.8. AUTHORISED REPRESENTATIVE IF APPLICABLE, NAME AND THE SRN

Not applicable.

1.9. NOTIFIED BODY’S NAME AND NB’S SINGLE IDENTIFICATION NUMBER

SGS Belgium NV
SGS House - Noorderlaan 87 (RPR Antwerpen BTW BE 0404.882.750)
Anvers, 2030
Belgique

The Single identification number of SGS is CE 1639.

2. INTENDED PURPOSE OF THE DEVICE

2.1. INTENDED USE AND INTENDED PURPOSE

BDyn is intended for orthopaedic spine surgery. The sterile spinal dynamic posterior stabilization devices BDyn is intended to restore the stabilization of the non-cervical segment of the spine by preserving the anatomical lordosis and the deadening of the intervertebral joint. It is composed of the BDyn spinal shock absorber fixed on the vertebrae thanks to the dedicated screws.

The main goals of the BDyn are :

- Induce the load sharing,
- Relieve the facets loads,
- Prevent the adjacent syndrome,
- Allow the combination with the fusion,

- Maintain the mobility and ensure the absorption of mechanical loads of the lumbar functional unit.

2.2. INDICATIONS AND TARGET POPULATION(S)

The sterile spinal dynamic posterior stabilization device BDyn is intended for posterior stabilization from thoracic vertebrae T10 to sacrum S1 with or without bone graft for the following indications:

- Degenerative intervertebral disc disease and/or articular facets confirmed by history and radiographic studies
- Spinal stenosis
- Spondylolisthesis grade 1
- Segmental instability

The Sterile Spinal Dynamic Posterior Stabilization device BDyn is only intended to skeletally mature adults.

2.3. CONTRAINDICATIONS AND/OR LIMITATIONS

The contra-indications are the following:

- Active infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Grossly distorted anatomy caused by congenital abnormalities
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of the sedimentation rate unexplained by other diseases, elevation of the white blood count
- Suspected or documented metal allergy or intolerance
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow postoperative instructions
- Any case not describe in the indications
- Traumas (i.e. fracture or dislocation)
- Abnormal curvatures (i.e. scoliosis and/or hyper lordosis)
- Tumors.
- Spondylolisthesis grade 2 and more
- Pseudarthrosis and/or failed previous fusion
- Severe bone resorption, osteomalacia, severe osteoporosis

3. DEVICE DESCRIPTION

3.1. DESCRIPTION OF THE DEVICE

3.1.1. GENERAL DESCRIPTION

BDyn is an intervertebral dynamic posterior stabilization device made of three titanium alloy (Ti6Al4V (90%Ti, 6%Al, 4%V) ELI = Extra Low Interstitial components) and two elastomer parts:

- a mobile rod,
- a fixed rod
- a cylindrical cover which protects the two elastomer parts, a ring made of polyurethane and a cushion made of silicone.

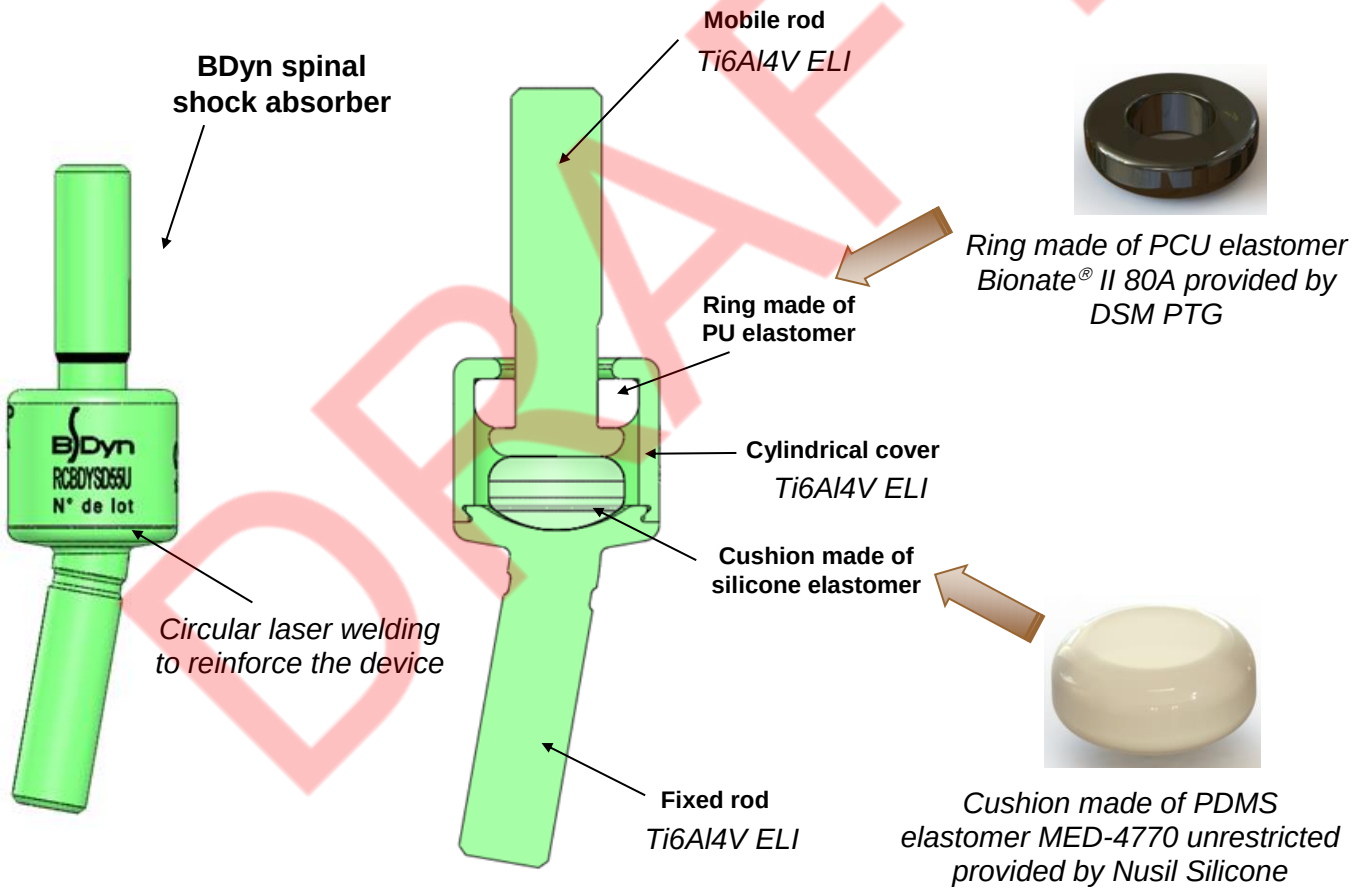

Figure 1 Isometric and cut view of the BDyn spinal shock absorber with its elastomer components

The BDyn spinal shock absorber can absorb the traction loads until 1 mm of displacement in traction thanks to the ring and the compression loads until 2 mm of displacement in compression thanks to the cushion.

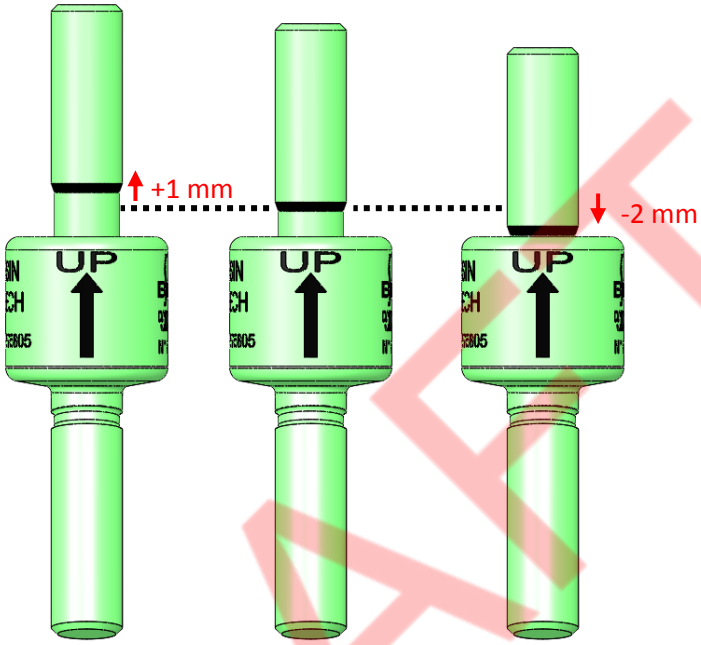

Figure 2 Traction-compression motion of the BDyn spinal shock absorber

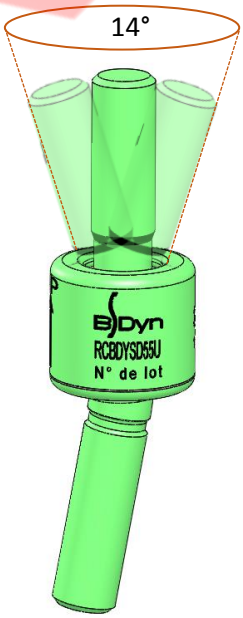

Figure 3 Flexion and polyaxiality of the BDyn spinal shock absorber

The mobile rod of the BDyn spinal shock absorber can rotate around its axis with a 14° angle of polyaxiality in neutral position. The range of BDyn spinal shock absorber is composed of 4 references:

The mobile rod of the BDyn spinal shock absorber can rotate around its axis with a 14° angle of polyaxiality in neutral position. The range of BDyn spinal shock absorber is composed of 5 references:

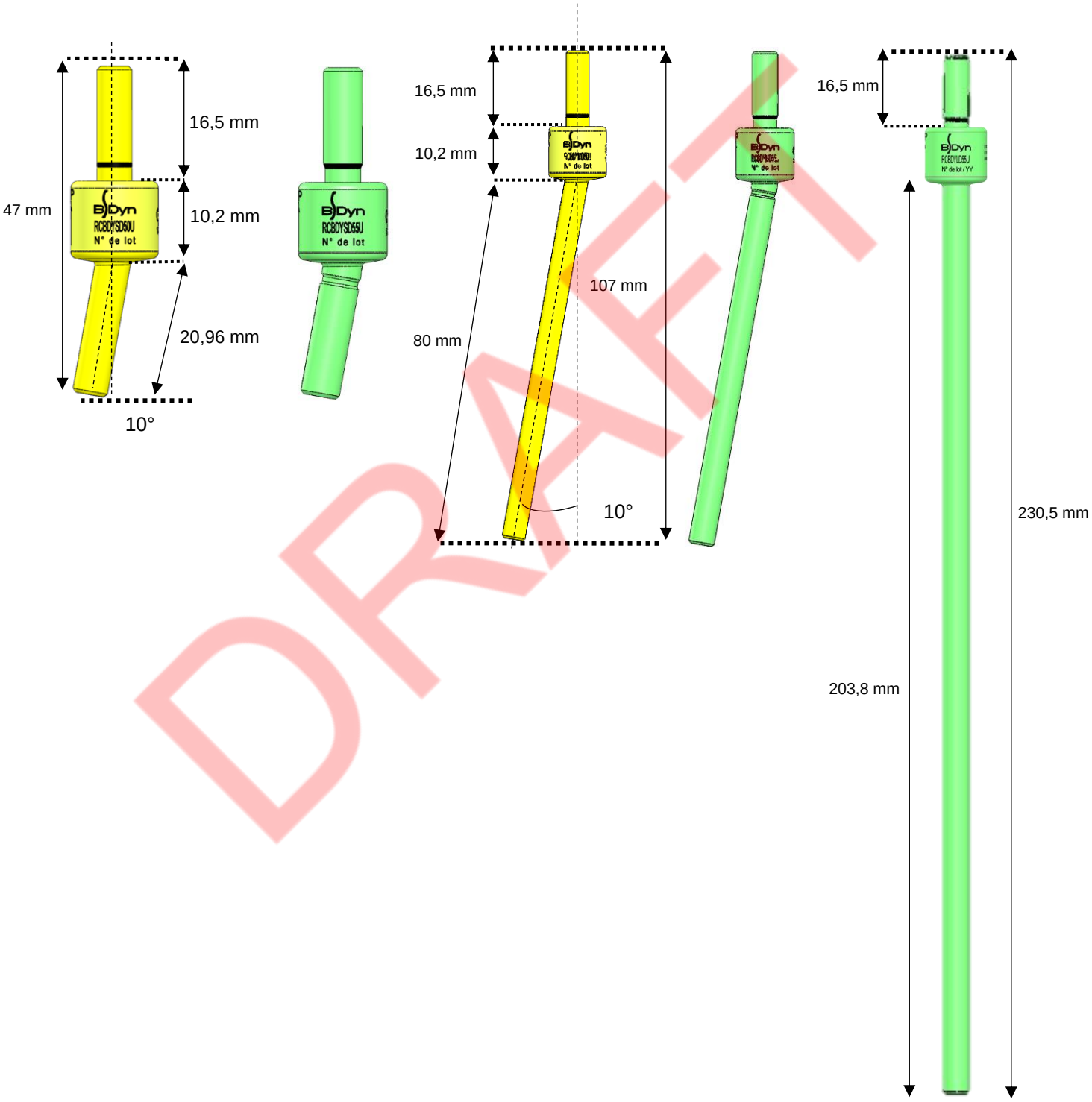

Figure 4 Range of BDyn spinal shock absorber

The fixed rod with an angle of 10° (except for RCBDYLD55U) is suitable to the anatomical lordosis, but it can be bent to improve its placement on the spine.

The BDyn belongs to the non-fusion spinal device. The references RCBDYSD50U and RCBDYSD55U can treat one functional unit by preserving the mobility and the flexibility and the references RCBDYMD50U and RCBDYMD55U allow to combine non fusion with the fusion of a maximum of two functional units of the spine. The RCBDYLD55U allow to cover 4 levels of fusion and one level of dynamic stabilization.

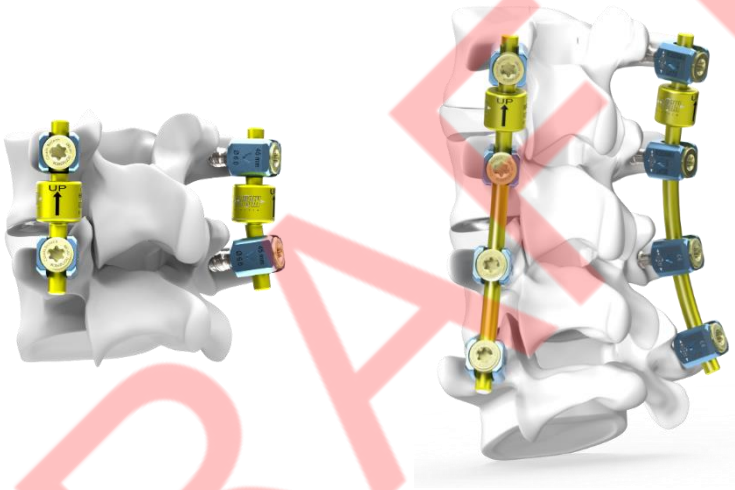

Figure 5 : BDyn reference (5.0 mm) – RCBDYSD50U (left) and RCBDYMD50U (right)

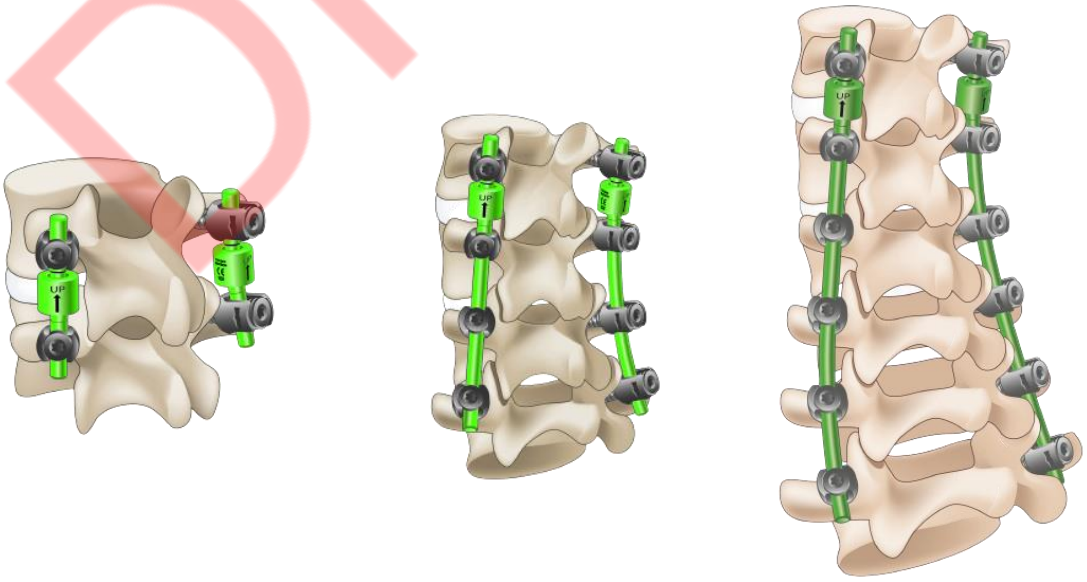

Figure 6 : BDyn reference (5.5 mm) fusion of a maximum of two functional units of the spine

3.1.2. LIST OF REFERENCES

Ref.	Picture
RCBDYSD50U	
RCBDYMD50U	
RCBDYSD55U	
RCBDYMD55U	
RCBDYLD55U	

Table 1 List of references

3.1.3. PRINCIPLES OF OPERATION

The BDyn implant is a medical device which can be used with pedicular screws as a fixation in vertebrae and intended for dynamic posterior stabilization of the spine.
The device is made of:

- A dynamic cylindrical body, containing 2 elastomers:

The silicone cushion allows motion preservation and works as a shock absorber that helps to decrease intradiscal pressure and to relieve facet loads during mechanical stress applied on the vertebrae.
The PCU ring limits the segmental instability of the spine segment.

- An upper and lower rods to be fixed into pedicular screws allowing a robust fixation of the device on the vertebrae.
- The caudal rod has a 10° angulation (except for the long-sized reference RCBDYLD55U) in order to fit the anatomical lordosis.
- If needed and depending on the surgeon's decision, a medium-sized device is available with a longer rigid rod for a combination with fusion of 1 or 2 lower segments.

Specific dimensions have been established during design development of the prosthesis to perfectly match the anatomy of the implanted site while limiting the cluttering. The choice of raw material allow rod bending and improves the conformability to the anatomical lordosis.
Furthermore, range of sized has been chosen in order to be adapted to validated polyaxial screws.

3.1.4. KEY FUNCTIONAL ELEMENTS

The BDyn spinal shock absorber of the Sterile Spinal Dynamic Posterior Stabilization Devices BDyn consists of a metallic cylindrical hollow part containing elastomer components made of silicone elastomers (polydimethyl siloxane (PDMS)) and long-term implantable polycarbonate urethane (PCU) which are bending out under the effect of a metallic piston rod connected with the vertebra of the treated segment by the pedicular screws tested and approved by the company COUSIN BIOTECH. The combination of rigid and flexible components helps to maintain the mobility and ensure the absorption of mechanical loads in flexion/extension, compression, axial rotation, and lateral bending. This ensures to reduce intradiscal pressure and relieve facets. Several configurations are available and allow the combination of dynamic and fusion solution.

3.1.5. MATERIALS AND CONTAINED SUBSTANCES

Duration of use or contact with the body
Long-term (permanent)

Materials or substances in contact with the patient tissues
The body part on which the device acts or with which it interacts

BRAND NAME	PART OF THE DEVICE	RAW MATERIALS (Commercial name)
BDyn Spinal Shock Absorber	Cylindrical cover	Titanium alloy - Ti6Al4V ELI ISO 5832-3 ASTM F 136
	Fixed rod	
	Fixed rod	
	Mobile semi rod piston	
	Cushion	Polydimethyl siloxane (PDMS) MED 4770 unrestricted - NUSIL
	Ring	Polycarbonate urethane (PCU) BIONATE® II 80A - DSM PTG

Table 2 Materials or substances in contact with the patient tissues fr BDyn

3.2. A REFERENCE TO PREVIOUS GENERATIONS OR VARIANTS IF SUCH EXIST AND A DESCRIPTION OF THE DIFFERENCES

Initially, the design of the current B-Dyn device comes from the improvement of a peadiatric EC marked product called “Growing Spine Profiler” (GSP) developed in 1999 by the company HEXABIO, then transferred to BIOSPINE Implants (S14 Implants) in 2005 and sold to the company Paradigme Spine in 2007. The aim of the GSP is to correct severe scolioses of young children according their growth by using a driving module and two rack rods fixed on the ribs with stirrups and on the vertebrea by small pedicular screws . In 2001, the GSP has been enhanced by the integration of a shock absorption rack rod.

Following the good clinical results, BIOSPINE Implants decided in 2008 to apply this technology and this design to a spinal dynamic stabilisation device by adapting the shock absorption rack rod of the GSP to the biomechanical requirements of the adult lumbar spine.

3.3. DESCRIPTION OF ANY ACCESSORIES WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

Accessories included : there are no accessories included with the Sterile Spinal Dynamic Posterior Stabilization Devices.

Accessories not included but necessary for use :

Under MDD, the instruments were classified as Class I. Note that the instruments are currently being submitted by the legal manufacturer in MDR with the new classification according to MDR 2017/45, Ire.

The reusable instruments used to implant this device are the following :

INSTRUMENTS REFERENCE	USE	Manufacturer
BDYNCONT00	Container	COUSIN BIOTECH
RCBANDH10U	Torque handle (10 N)	COUSIN BIOTECH
RCBANSOUNU	Reversible probe	COUSIN BIOTECH
RCBANRH50U	Rod holder	COUSIN BIOTECH
RCBANLPERU	Lumbar perforator	COUSIN BIOTECH
RCBANTPERU	Thoracic perforator	COUSIN BIOTECH
RCBANLRBEU	Bender	COUSIN BIOTECH
RCBANDISTU	Distraction Clamp	COUSIN BIOTECH
RCBANCOMPU	Contraction Clamp	COUSIN BIOTECH
RCBANTD50U	Trial implant	COUSIN BIOTECH
RCBANBDHOU	BDyn holder	COUSIN BIOTECH
RCBANRODPU	Rod pusher	COUSIN BIOTECH
014112C	Square Tip	NEURO FRANCE Implants
013615	Cannulated Tap 5.0	NEURO FRANCE Implants
011300	Fork	NEURO FRANCE Implants
911537	Kirschner wire	NEURO FRANCE Implants
013001N	Straight ratchet cannulated handle	NEURO FRANCE Implants
010201C	Cannulated screwdriver	NEURO FRANCE Implants
010494	Nut holder	NEURO FRANCE Implants
010505C	Nut driver	NEURO FRANCE Implants
011308	Persuader	NEURO FRANCE Implants
010001N	Ratchet cannulated T-handle	NEURO FRANCE Implants
013616	Cannulated Tap 6.0	NEURO FRANCE Implants
010610C	Counter-torque	NEURO FRANCE Implants
016103	One-way probe	NEURO FRANCE Implants

3.4. DESCRIPTION OF ANY OTHER DEVICES AND PRODUCTS WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

No other devices are intended to be used in combination with BDyn implants in addition to generic surgical instruments.

4. RISKS AND WARNINGS

4.1. RESIDUAL RISKS AND UNDESIRABLE EFFECTS

All of the possible adverse events associated with spinal surgery and without instrumentation are possible:

- Infection
- Pseudomeningocele, fistula, breach dura, persistent CSF leakage, meningitis
- Loss of neurological function, sensorial and/or motor, including complete or incomplete paralysis, dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits
- Cauda equina syndrome, neuropathy, transient or permanent neurological deficits, paraplegia, paraparesis, reflex deficits, irritation, arachnoïditis, and/or muscle loss
- Urinary retention or loss of bladder control or other types of urological system compromise

- Scar formation possibly causing by a neurological compromise or compression around nerves and/or pain
- Fracture, microfracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery, canal adjacent stenosis
- Non-union or pseudarthrosis, delayed union. Mal union
- Cessation of any potential growth of the operated portion of the spine
- Loss of or increase in spinal mobility or function
- Inability to perform the activities of daily living
- Bone loss or decrease in bone density
- Graft donor site complications including pain, fracture, or wound healing problems
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise
- Hemorrhage, hematoma, occlusion, seroma, oedema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise
- Reproduction system compromise, sterility, sexual dysfunction
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc
- Change in mental status
- Death

All of the possible adverse events associated with spinal surgery with instrumentation are possible. A listing of potential adverse events linked to the medical device includes, not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending and/or breakage of any or all of the components (screw breakage)
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, tumor formation and/or autoimmune disease
- Pressure on the skin from components parts with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain
- Tissue or nerve damage caused by improper positioning and placement of implants or instrument
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction

4.2. WARNINGS AND PRECAUTIONS

The BDyn devices are delivered sterile, sterilized by ethylene oxide.
Before any use, inspect the integrity of the packaging and device (including peelable pouches).
Do not use in the event of deterioration of the labels and/or the device and/or the packaging.
Do not use if the device is out of date.
The installation of BDyn device can only be made with pedicular screws tested and approved by the company COUSIN BIOTECH.
You should never use implants made of stainless steel and titanium alloy in the same construct.
Many factors must be considered during spinal surgery, which means that the results obtained are highly variable. This device, like all spinal implants, can only withstand the loads of the body if it is in addition to a bone structure. In the case of alteration of the bone support, loosening, disassembly and/or rupture of the device may occur. Preoperative and operating procedures, including precise knowledge of suitable surgical

techniques, and proper selection of the good reference of the device adapted to the patient and its narrow setting up are important considerations in the successful use of the device by the surgeon.
The BDyn device must be implanted only by a qualified surgeon, having knowledge in the use of the product and who has the knowledge of the anatomy, spinal surgery, pedicle screws fixation technique and specific BDyn device surgical technique.

4.3. OTHER ASPECTS OF SAFETY INCLUDING A SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION IF APPLICABLE

ANSM has been informed of two batch recalls by the company S14 in 2016 and 2017 respectively.

Identification of document	Type of incident
Agence Nationale de Sécurité du Médicaments et des Produits de Santé, A., 2016. Chirurgie du rachis - Implant rachidien B-DYN - Biospine Implants/S14 Implants - Rappel.	Biospine Implants has identified that the cleaning validation, has not been correctly documented according to the standard S94-091. Therefore, the conformity of the cleaning process with the standard cannot be demonstrated.
Agence Nationale de Sécurité du Médicaments et des Produits de Santé, A., 2017a. Chirurgie du rachis - Implant rachidien B-DYN - Biospine Implants/S14 Implants - Rappel.	The routine packaging tests ordered by Biospine Implants, concludes that the packaging of the concerned medical devices is not fully compliant with all the acceptance criteria. Therefore, the complete conformity of the packaging for the concerned medical devices with the applicable standards cannot be completely demonstrated.

No FSCA since the takeover of the BDyn by COUSIN BIOTECH in November 2017.

5. SUMMARY OF CLINICAL EVALUATION AND INFORMATION ON POST-MARKET CLINICAL FOLLOW-UP

5.1. SUMMARY OF OTHER CLINICAL DATA RELATED TO EQUIVALENT DEVICE, IF APPLICABLE

Not Applicable.

5.2. SUMMARY OF CLINICAL PERFORMANCE AND SAFETY

5.2.1. SUMMARY OF CLINICAL DATA FROM CONDUCTED INVESTIGATIONS OF THE DEVICE BEFORE THE CE-MARKING, IF APPLICABLE

Not applicable.

5.2.2. SUMMARY OF CLINICAL DATA FROM OTHER SOURCES, IF APPLICABLE

5.2.2.1. CLINICAL DATA

The update of the literature search performed in the last clinical evaluation report allowed the identification of clinical evidence pertaining to the evaluated device.
The reference and summary of the clinical data retrieved from systematic reviews yielding articles in which the medical device was used is presented in this section.

DATA SOURCE	DESCRIPTION	MAIN RESULTS
Clinical Data from the manufacturer		
PMCF Study (Fortin et al., 2015; Poulette et al., 2018)	Retrospective observational clinical study N = 114 patients	Significant decreases of mean preoperative VAS and ODI values were observed from 3-6 months up to 4 years of follow-up (p-values < 0.001). The efficacy rate was 63.2% (CI 95% [52.3% – 74.0%]) in accordance with the primary efficacy endpoint (radicular and lumbar VAS decreases and ODI improvement ≥15). Among the 114 patients of the Tolerance population, 41 (36%) complications related (or likely to be related) to the device or its placement were reported, including 8 (7.0%) patients with device deficiencies (5 with screwbreakages, 1 with rod and screw breakages and 2 device malpositions). As a consequence of these complications, 19 (16.7%) surgical revisions were reported.
Clinical Data from the literature		
(Serratrice et al., 2022)	Monocentric randomized clinical trial N = 50 patients	The BDYN system appears safe, well-tolerated, and could be an effective alternative to fusion techniques in the treatment of patients with low-grade lumbar degenerative spondylolisthesis while preserving motion and theoretically preserving the adjacent vertebral segment. **Clinically:** 80% (40 patients) had a satisfying functional result in terms of daily life activity, pain and walking distance, and 20% (10 patients) were considered as having a poor outcome according to the ODI score.
Clinical datasets of clinical interest		
Users survey: BDYN_SURVEY REPORT_2020-07-15	N = 207	*Indications* 28,57% of the users who replied to the questionnaire used BDYN for the indication "Degenerative intervertebral disc disease and/or articular facets confirmed by further examinations" 28,57% of the users who replied to the questionnaire used BDYN for the indication "Spinal canal stenosis" 85,71% of users who replied to the questionnaire used BDYN for the indication "Degenerative spondylolisthesis grade 1" 57,14% of users who replied to the questionnaire used BDYN for the indication "Segmental instability" *Safety* REOPERATIONS AND EXPLANTATIONS: Out of the seven (7) responses to the questionnaire, none of the surgeons experienced a reoperation following a BDYN implantation and O BDYN implants were explanted. SCREW BREAKAGE: Since November 2017, none of the surgeons experienced a breakage of the Cousin Biotech screw. ADVERSE EVENTS: Out of the seven (7) responses to the questionnaire, none of the surgeons reported any adverse events.

Users survey: BDYN_SURVEY REPORT_2022-07-26	N = 409	*Indications* The most frequent indication is: - "Degenerative spondylolisthesis grade 1" for 40% of users who replied to the questionnaire - "Degenerative intervertebral disc disease and/or articular facets confirmed by further examinations" for 40% of users who replied to the questionnaire - "Spinal canal stenosis" for 20% of users who replied to the questionnaire *Surgical reintervention and explantation* Three (3) of these surgeons experienced explantations afterwards. In total, 18 explantations were reported (4.4%). *Undesirable side effects* All reported undesirable side effects are well known and expected for this type of surgery. No other undesirable side effects have been reported by the interviewed surgeons.
(Eurospine, 2023)	134	The ODI index mean score has been improved. No benefit was reported.
(Homa, 2024)	41	Patients were operated at a mean age of 59.0 ± 12.9 years (Minimum 33 years-old and maximum 84 years-old) with a majority of women (61.0% vs 39.0%). Degenerative disc disease was the first cause of surgery in this registry ((46.3%), followed by degenerative spondylolisthesis (26.8%), facet joint arthrosis (34.1%), central stenosis (26.8%) and disc herniation (19.5%). Radicular pain was at 7.3 ± 2.2 before surgery and stayed extremely low after surgery with a mean of 0.1 ± 0.3 at Visit 1, 0.1 ± 0.3 at Visit 2, 0.4 ± 1.5 at Visit 3 and even at 0 for all patients at Visit 4. Lumbar pain was at 7.7 ± 1.2 before surgery and stayed extremely low after surgery with a mean of 0.2 ± 0.6 at Visit 1, 0.2 ± 0.4 at Visit 2, 0.3 ± 0.8 at Visit 3 and 0.6 ± 1.2 at Visit 4. ODI score vary at last follow-up visit (9.6 ± 0.9 years; with a minimum of 8.2 years and a maximum of 11.1 years follow-up). Mean ODI score was 14.2 ± 9.6 (on a 100-scale), with a minimum of 0 and a maximum of 37/100. No patients returned to work at Visit 1 (0%), at visit 2, 66.7% of patients returned partially or fully to work, 82.6% at Visit 3 and 100% of the 7 patients from Visit 4 returned partially or fully to work. In this study, 2 patients presented ASD (4.9%) with no reintervention needed. Overall, all early and late complications observed in this study were expected. 3 patients (7.3%) experienced dural lesions during procedure, with 100% resolved with suture during surgery. One patient experienced early post operation complication before discharge. This patient (2.4%) experienced hematoma that needed to be evacuated two days after surgery. Intraoperative complications rate was lower than the one (27.27%) observed in literature. This present study highlights good safety and performance after BDyn implantation up to 9.6 ± 0.9 years of follow-up.

5.2.2.2. PMS DATA

31 complaints regarding the Sterile Spinal Dynamic Posterior Stabilization Device have been notified since 2008. Among these 31 complaints, 18 concern BDyn ancillaries and BDyn screws.
To date, the screws used with BDyn devices are manufactured by Neuro France Implants.

Among these 13 complaints regarding BDyn product, only 1 concerned a serious product incident (device breakage).

The total number of customer complaints concerning BDyn is very low compared to number of products sold: 0.0009%. The PMS did not identify any trend nor serious problem.

Based on the low frequency of complaints, the safety profile of the implants is confirmed.

5.2.3. CONCLUSIONS ON CLINICAL PERFORMANCE AND SAFETY REQUIREMENTS

In accordance with MDR 2017/745 UE, and with the PMS procedure, a post-marketing surveillance plan has been established. This plan describes the activities implemented by COUSIN BIOTECH to continually update the data presented in this Clinical Evaluation Report and in particular:

- The acceptability of the risk benefit ratio compared to the state of the art and current clinical knowledge, and therapeutic alternatives.
- The adequacy of the information provided with the device compared to expectations in terms of instructions and risk management measures.
- The suitability of the device (including the information of the IFU) in relation to the clinical needs of the target users and the usability of the products.
- Consistency of performances and benefits claimed by the COUSIN BIOTECH for the device based on available clinical data

5.3. ONGOING POST MARKET CLINICAL FOLLOW-UP

For the Sterile Spinal Dynamic Posterior Stabilization Devices, there are:

- An on-going randomized prospective PMCF study “MOVESTAR” : “Efficacy and tolerance of the B-Dyn medical device compared to a conventional bolted fusion with or without cage in the treatment of degenerative lumbar stenosis”.

- Participation to the registry “Spine Tango”. This registry permit to collect data to monitor safety and performance of BDyn. Clinical data are being collected retrospectively in the registry.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Nonsurgical approaches :
Non-surgical options include drugs, physiotherapy, spinal injections, lifestyle modification, and multidisciplinary rehabilitation. It is generally admitted in the guidelines that these approaches should always be considered as first choice given the limited level of demonstration of the benefit of surgical technique on the long term. Conservative interventions also appear to reduce fear (especially fear of falls) amongs patients with low back pain.

Nevertheless, when all applicable non-surgical approaches have been tried and failed for at least several months, invasive approaches can be proposed, with a careful weighing of the benefit risk of the intervention for the patient.

Invasive / Surgical approaches

In the majority of cases, spinal disc herniation articular facets syndrome doesn't require surgery. Surgery may be useful in those with a herniated disc that is causing pain and neurological symptoms in the lower limbs. (NASS guidelines). If there is incontinence, weakness and genital numbness (Cauda Equina syndrome) it is considered a medical emergency requiring immediate attention and possibly surgical decompression.

Several techniques are described in the literature:

- **Discectomy** (removal some or all of a damaged disc, which can be helpful if it's pressing on a nerve).
- **Fusion surgery** (in case of a severely damaged disc, it may be removed. To re-stabilize this part of the spine, the surrounding vertebrae are fused (permanently joined) together).
- **Artificial disc replacement** (The damaged disc is removed and replaced with an artificial, or prosthetic, disc.)

7. SUGGESTED PROFILE AND TRAINING FOR USERS

As specified in Instructions for Use *"The BDyn device must be implanted only by a qualified surgeon, having knowledge in the use of the product and who has the knowledge of the anatomy, spinal surgery, pedicle screws fixation technique and specific BDyn device surgical technique."*

For training of first-time users, we propose to the surgeon to participate to a cadaver course and/or to a workshop in one of our international Excellence Center (peer to peer training). During cadaver course, first part is theorical revue is around genesys of the implant, biomechanics, clinical case review and litterature; second part is practice : on sawbones to review the surgical technique followed by practice on cadaver. During workshop, a case review is organized with the trainer (surgeon) followed by an assistance in OR to attend BDyn surgeries. We also organize for all 1st surgery a staff meeting with the sales reps of the area and operating room assistance by the sales reps. All our sale reps (direct in France or for worldwide market are trained on the product; all sales reps from our international distribution are also trained).

8. REFERENCE TO ANY HARMONISED STANDARDS AND COMMON SPECIFICATIONS APPLIED

All Harmonized Standards applicable to the Device are applied in full :

• The compliance of included dataset has been checked.
• If compliance with the Standards of good clinical practices was not claimed by the authors, proof of approval by ethic committee and quality of data have been searched whenever applicable and recorded.
Harmonized standards following Regulation (EU) 2017/745 are identified with " * ", in the present document.

*EN ISO 13485:2016/A11:2021 - Medical Devices - Quality Management Systems - Requirements for Regulatory purposes
NF EN ISO 9001 - Quality Management Systems - Requirements
NF EN ISO/IEC 17025:2017 - General requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, nonstandard methods, and laboratory-developed methods
NF EN ISO 14 630:2013 - Non-active surgical implants - General requirements
NF EN 1041+A1:2013 - Information supplied by the manufacturer of medical devices
EN ISO 15223:2016 - Medical devices – Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements *EN ISO 15223:2021 - Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1 : General requirements
*EN ISO 14971:2019 - Medical devices – Application of risk management to medical devices
NF EN 62366-1:2015 Amd 1:2020 - Medical Devices - Application of usability engineering to medical devices
NF EN ISO 10993-1:2020 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
NF EN ISO 10993- 3:2014 - Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
NF EN ISO 10993- 5:2010 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2017 - Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-7/A1:2019 - Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
NF EN ISO 10993-10:2013 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization *ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
NF EN ISO 10993-11:2018 - Biological evaluation of medical devices. Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012 : Biological evaluation of medical devices. Part 12: Sample preparation and reference materials *EN ISO 10993-12: 2021 - Biological evaluation of medical devices. Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009 - Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
NF EN ISO 10993-18:2020 - Biological evaluation of medical devices. Part 18: Chemical Characterization of materials
*EN ISO 11607- 1 :2020 - Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

*EN ISO 11607-2 :2020 - Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 556-1:2001/AC:2006 - Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices
*EN ISO 11737-1:2018/A1 2021 - Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
*EN ISO 11737-2 :2020 - Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
*EN ISO 11135-1:2014 (+A1:2019) - Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11138-2:2017 - Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
NF ISO 19227:2018 - Implants for surgery - Cleanliness of orthopedic implants - General Requirements -
NF 868-5 - Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
*NF EN ISO 14155:2020 - Clinical investigation of medical devices for human subjects - Good clinical practice
NF EN ISO 14 698-1 - Cleanrooms and associated controlled environments - Biocontamination control - Part 1 : General principles and methods
NF EN ISO 19 011 - Guideline for auditing management systems
NF ISO 2859-1/A1 - Sampling procedures for inspection by attributes – Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection
NF EN ISO 14644-1 - Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle
NF EN ISO 14644-2 - Cleanrooms and associated controlled environments— Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
NF EN ISO 14644-3 - Cleanrooms and associated controlled environments—Part 3: Tests methods
ISO 12189 - Implants for surgery - Mechanical testing of implantable spinal devices - Fatigue test method for spinal implant assemblies using an anterior support
NF ISO 12891-1 - Retrieval and analysis of surgical implants - Part 1 : Retrieval and handling
ISO TR 20416:2020 - Medical devices — Post-market surveillance for manufacturers

No common specifications have been identified for the moment.

SECTION 2: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE FOR PATIENTS

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. A summary intended for patients can be found in Section 2.

1. IDENTIFICATION OF THE DEVICE AND GENERAL INFORMATION

1.1. DEVICE TRADE NAME(S)

The device under evaluation is marketed under the following trade name: BDyn.

1.2. MANUFACTURER'S NAME AND ADDRESS

COUSIN BIOTECH
Allée des Roses
59117 Wervicq-Sud
FRANCE

1.3. MANUFACTURER'S SRN

The Single Registration Number (SRN) of the manufacturer is FR-MF-000001179.

1.4. BASIC UDI-DI

To enable the traceability of the medical device, the manufacturer has already defined the Basic UDI-DI specific to medical device which is 375018557BDYNSPINALIMPM4.

1.5. YEAR WHEN THE FIRST CERTIFICATE WAS ISSUED COVERING THE DEVICE

The products concerned by this EC marking file have been initially developed, EC marked and then commercialized under the name "BDyn" by the company BIOSPINE Implants (S14 Implants) from November 2008 to January 2017.
In 2017, the company COUSIN BIOTECH bought the BDyn to relaunch them on the market.

1.6. CLASS OF DEVICE

All the Sterile Spinal Dynamic Posterior Stabilization Devices included in this CE technical file are in Class III according to the Annex VIII, chapiter III, Rule 8 dash 9 of the classification criteria of the Regulation (EU) No 2017/745.

1.7. YEAR WHEN THE FIRST CERTIFICATE (CE) WAS ISSUED COVERING THE DEVICE

The first CE certificate of the BDyn manufactured by Cousin Biotech is dated from the 2nd of February 2017.

1.8. AUTHORISED REPRESENTATIVE IF APPLICABLE, NAME AND SRN

Not applicable.

1.9. NOTIFIED BODY'S NAME AND SRN

The notified body's name is SGS.

2. INTENDED PURPOSE OF THE DEVICE

2.1. INTENDED PURPOSE AND INTENDED USE

BDyn is intended for orthopaedic spine surgery. The sterile spinal dynamic posterior stabilization devices BDyn is intended to restore the stabilization of the non-cervical segment of the spine by preserving the anatomical lordosis and the deadening of the intervertebral joint. It is composed of the BDyn spinal shock absorber fixed on the vertebrae thanks to the dedicated screws.

The main goals of the BDyn are :

- Induce the load sharing,
- Relieve the facets loads,
- Prevent the adjacent syndrome,
- Allow the combination with the fusion,
- Maintain the mobility and ensure the absorption of mechanical loads of the lumbar functional unit.

2.2. INDICATIONS AND TARGET POPULATION(S)

The sterile spinal dynamic posterior stabilization device BDyn is intended for posterior stabilization from thoracic vertebrae T10 to sacrum S1 with or without bone graft for the following indications:

- Degenerative intervertebral disc disease and/or articular facets confirmed by history and radiographic studies
- Spinal stenosis
- Spondylolisthesis grade 1
- Segmental instability

The Sterile Spinal Dynamic Posterior Stabilization device BDyn is only intended to skeletally mature adults.

2.3. CONTRAINDICATIONS

The BDyn implant should not be employed in :

- Active infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness

- Grossly distorted anatomy caused by congenital abnormalities
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of the sedimentation rate unexplained by other diseases, elevation of the white blood count
- Suspected or documented metal allergy or intolerance
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow postoperative instructions
- Any case not describe in the indications
- Traumas (i.e. fracture or dislocation)
- Abnormal curvatures (i.e. scoliosis and/or hyper lordosis)
- Tumors.
- Spondylolisthesis grade 2 and more
- Pseudarthrosis and/or failed previous fusion
- Severe bone resorption, osteomalacia, severe osteoporosis

3. DEVICE DESCRIPTION

3.1. DESCRIPTION OF THE DEVICE

3.1.1. GENERAL DESCRIPTION

BDyn is an intervertebral dynamic posterior stabilization device made of three titanium alloy and two elastomer parts: a mobile rod, a fixed rod a cylindrical cover which protects the two elastomer *(a polymer with "elastic" properties)* parts, a ring and a cushion.

The BDyn spinal shock absorber can absorb the traction loads until 1 mm of displacement in traction thanks to the ring and the compression loads until 2 mm of displacement in compression thanks to the cushion.

The BDyn belongs to the non-fusion spinal device. The references with small rods can treat one functional unit by preserving the mobility and the flexibility and the references with medium rods allow to combine non fusion with the fusion of a maximum of two functional units of the spine.

3.1.2. LIST OF REFERENCES

Ref.	Picture
RCBDYSD50U	

RCBDYMD50U	
RCBDYSD55U	
RCBDYMD55U	
RCBDYLD55U	

Table 3 List of references

3.1.3. PRINCIPLES OF OPERATION

The BDyn implant is a medical device which can be used with pedicular screws as a fixation in vertebrae and intended for dynamic posterior stabilization of the spine.
The device is made of:

- A dynamic cylindrical body, containing 2 elastomers:

The silicone cushion allows motion preservation and works as a shock absorber that helps to decrease intradiscal pressure and to relieve facet loads during mechanical stress applied on the vertebrae.
The PCU ring limits the segmental instability of the spine segment.

- An upper and lower rods to be fixed into pedicular screws allowing a robust fixation of the device on the vertebrae.
- The caudal rod has a 10° angulation (except for the long-sized reference RCBDYLD55U) in order to fit the anatomical lordosis.
- If needed and depending on the surgeon's decision, a medium-sized device is available with a longer rigid rod for a combination with fusion of 1 or 2 lower segments.

Specific dimensions have been established during design development of the prosthesis to perfectly match the anatomy of the implanted site while limiting the cluttering. The choice of raw material allow rod bending and improves the conformability to the anatomical lordosis.
Furthermore, range of sized has been chosen in order to be adapted to validated polyaxial screws.

3.1.4. KEY FUNCTIONAL ELEMENTS

The BDyn spinal shock absorber of the Sterile Spinal Dynamic Posterior Stabilization Devices BDyn consists of a metallic cylindrical hollow part containing elastomer components made of silicone elastomers (polydimethyl siloxane (PDMS)) and long-term implantable polycarbonate urethane (PCU) which are bending out under the effect of a metallic piston rod connected with the vertebra of the treated segment by the pedicular screws tested and approved by the company COUSIN BIOTECH. The combination of rigid and flexible components helps to maintain the mobility and ensure the absorption of mechanical loads in flexion/extension, compression, axial rotation, and lateral bending. This ensures to reduce intradiscal pressure and relieve facets. Several configurations are available and allow the combination of dynamic and fusion solution.

3.1.5. MATERIALS AND CONTAINED SUBSTANCES

Duration of use or contact with the body
Long-term (permanent)

Materials or substances in contact with the patient tissues
The body part on which the device acts or with which it interacts

BRAND NAME	PART OF THE DEVICE	RAW MATERIALS (Commercial name)
BDyn Spinal Shock Absorber	Cylindrical cover	Titanium alloy - Ti6Al4V ELI ISO 5832-3 ASTM F 136
	Fixed rod	
	Fixed rod	
	Mobile semi rod piston	
	Cushion	Polydimethyl siloxane (PDMS) MED 4770 unrestricted - NUSIL
	Ring	Polycarbonate urethane (PCU) BIONATE® II 80A - DSM PTG

Table 4 Materials or substances in contact with the patient tissues for BDyn

3.2. A REFERENCE TO PREVIOUS GENERATIONS OR VARIANTS IF SUCH EXIST AND A DESCRIPTION OF THE DIFFERENCES

Initially, the design of the current B-Dyn device comes from the improvement of a peadiatric EC marked product called “Growing Spine Profiler” (GSP) developed in 1999 by the company HEXABIO, then tranfered to BIOSPINE Implants (S14 Implants) in 2005 and sold to the company Paradigme Spine in 2007. The aim of the GSP is to correct severe scolioses of young children according their growth by using a driving module and two rack rods fixed on the ribs with stirrups and on the vertebrea by small pedicular screws . In 2001, the GSP has been enhanced by the integration of a shock absorption rack rod.

Following the good clinical results, BIOSPINE Implants decided in 2008 to apply this technology and this design to a spinal dynamic stabilisation device by adapting the shock absorption rack rod of the GSP to the biomechanical requirements of the adult lumbar spine.

3.3. DESCRIPTION OF ANY ACCESSORIES WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

Not applicable.

3.4. DESCRIPTION OF ANY OTHER DEVICES AND PRODUCTS WHICH ARE INTENDED TO BE USED IN COMBINATION WITH THE DEVICE

Accessories included : there are no accessories included with the Sterile Spinal Dynamic Posterior Stabilization Devices.

Accessories not included but necessary for use : Specific instruments *(surgical instrument designed to assist the surgeon in measuring angles or distances with great accuracy when necessary)* have to be used to implant the sterile spinal dynamic stabilisation device BDyn.

4. RISKS AND WARNINGS

4.1. RESIDUAL RISKS AND UNDESIRABLE EFFECTS

All of the possible adverse events associated with spinal surgery and without instrumentation are possible:

- Infection
- Pseudomeningocele, fistula, breach dura, persistent CSF leakage, meningitis
- Loss of neurological function, sensorial and/or motor, including complete or incomplete paralysis, dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits
- Cauda equina syndrome, neuropathy, transient or permanent neurological deficits, paraplegia, paraparesis, reflex deficits, irritation, arachnoïditis, and/or muscle loss
- Urinary retention or loss of bladder control or other types of urological system compromise
- Scar formation possibly causing by a neurological compromise or compression around nerves and/or pain

- Fracture, microfracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery, canal adjacent stenosis
- Non-union or pseudarthrosis, delayed union. Mal union
- Cessation of any potential growth of the operated portion of the spine
- Loss of or increase in spinal mobility or function
- Inability to perform the activities of daily living
- Bone loss or decrease in bone density
- Graft donor site complications including pain, fracture, or wound healing problems
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise
- Reproduction system compromise, sterility, sexual dysfunction
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc
- Change in mental status
- Death

All of the possible adverse events associated with spinal surgery with instrumentation are possible. A listing of potential adverse events linked to the medical device includes, not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending and/or breakage of any or all of the components (screw breakage)
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, tumor formation and/or autoimmune disease
- Pressure on the skin from components parts with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain
- Tissue or nerve damage caused by improper positioning and placement of implants or instrument
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction

4.2. WARNINGS AND PRECAUTIONS

The BDyn devices are delivered sterile, sterilized by ethylene oxide.
Before any use, inspect the integrity of the packaging and device (including peelable pouches).
Do not use in the event of deterioration of the labels and/or the device and/or the packaging.
Do not use if the device is out of date.
The installation of BDyn device can only be made with pedicular screws tested and approved by the company COUSIN BIOTECH.
You should never use implants made of stainless steel and titanium alloy in the same construct.
Many factors must be considered during spinal surgery, which means that the results obtained are highly variable. This device, like all spinal implants, can only withstand the loads of the body if it is in addition to a bone structure. In the case of alteration of the bone support, loosening, disassembly and/or rupture of the device may occur. Preoperative and operating procedures, including precise knowledge of suitable surgical techniques, and proper selection of the good reference of the device adapted to the patient and its narrow setting up are important considerations in the successful use of the device by the surgeon.

The BDyn device must be implanted only by a qualified surgeon, having knowledge in the use of the product and who has the knowledge of the anatomy, spinal surgery, pedicle screws fixation technique and specific BDyn device surgical technique.

4.3. OTHER ASPECTS OF SAFETY INCLUDING A SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION IF APPLICABLE

Two field safety corrective actions have been reported in 2016 and 2017 when BDyn belonged to S14.
Products with defects are not recommended to be used as indicated in the precautions.
These risks are mentioned in the risk analysis and considered acceptable after risk reduction. These actions were integrated in the post-market surveillance documentation of the manufacturer. No new field action has been implemented since 2017.

5. SUMMARY OF CLINICAL EVALUATION AND INFORMATION ON POST-MARKET CLINICAL FOLLOW-UP

5.1. SUMMARY OF CLINICAL DATA RELATED TO EQUIVALENT DEVICE, IF APPLICABLE

Not applicable – the device was not CE marked based on an equivalent device.

5.2. CLINICAL EVIDENCE FOR THE CE MARKING

The total experience with the device is detailed below:

- On the market : Since the launch in 2017, 8578 units were sold and considered to be implanted in the patient.
- In clinical studies : In the retrieved clinical studies, 186 were estimated to receive BDyn.
- In users surveys and registries : In the user survey, 582 patients were estimated to receive the medical device.

Overall, the estimated number of patients which have available data for this clinical evaluation report is 9346.

Results of internal data from the literature

Citation	Bibliographic reference
Serratrice et al., 2022	Serratrice N, Faddoul J,Tarabay B, Obeid I, Abi Lahoud GN. Radiological factors affecting functional outcome after the implantation of BDYN™ dynamic stabilization system for low-grade lumbar degenerative spondylolisthesis. Publication under finalisation.

Data from survey and registries

Reference	Title
BDYN_SURVEY REPORT_2020-07-15	Preliminary PMCF report Sterile Spinal Dynamic Posterior Stabilization Devices
BDYN_SURVEY REPORT_2022-07-26	Clinical Follow-Up Survey Report Sterile Spinal Dynamic Posterior Stabilization Device – BDyn
(Eurospine, 2023)	Implant Report for COUSIN BIOTECH. BDyn Implants (Lumbar).

(Homa, 2024)	BDyn report from spine Tango registry. Patients' long-term outcome after BDyn device fixation : a nine-year follow-up case-series report.

PMCF studies :

Title	Tested products	Locations	Publication/Report
B-Dyn : Stabilisation dynamique dans le traitement des maladies spinales dégénératives	BDyn	Clinique du Pré (Le Mans) and Service Orthopédie - Groupe Hospitalier Pellegrin C.H.U. de Bordeaux	Report (Fortin et al., 2015; Poulette et al., 2018)
SPONGIT 2.0 Comparaison de deux stratégies chirurgicales dans le traitement du Spondylolisthésis Dégénératif (SLD) Lombaire L4-L5, de grade 1 : Système de stabilisation Dynamique B-Dyn® versus Arthrodèse (fusion).	BDyn	Service Orthopédie - Groupe Hospitalier Pellegrin C.H.U. de Bordeaux	Protocol (Gille, 2017) Referred as NCT00869882 in ClinicalTrial.gouv To date, no data available.
Study of the efficacy and tolerance of the B-Dyn medical device compared to a conventional bolted fusion with or without cage in the treatment of degenerative lumbar stenosis, with or without grade I spondylolisthesis on the degree of postoperative functional disability, preservation of mobility and prevention of the adjacent syndrome	BDyn vs Cage	Bordeaux hospital (France) and Cornebarrieu hospital (France)	MOVESTAR (Pointillart et al., 2024). Referred as NCT04407338 in ClinicalTrial.gouv and in Cochrane Library.

5.3. SAFETY

Regarding safety, there are a number of undesirable effects following implantation of the device which have been identified and previously described (see §4.2). These events are all expected, and their frequency are within or below what is described in current literature as shown in the table below.

Undesirable side effect	Expected (SOTA)	Observed (clinical studies and survey)
Pseudomeningocele, fistula, breach dura, persistent CSF leakage, meningitis	Mentioned but frequency not described	27.27%
Loss of neurological function, sensorial and/or motor, including complete or incomplete paralysis, dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits	0.46-24%	4.9%

Cauda equina syndrome, neuropathy, transient or permanent neurological deficits, paraplegia, paraparesis, reflex deficits, irritation, arachnoïditis, and/or muscle loss	Mentioned but frequency not described	-
Urinary retention or loss of bladder control or other types of urological system compromise	0.22%-40%	-
Scar formation possibly causing by a neurological compromise or compression around nerves and/or pain	Mentioned but frequency not described	-
Fracture, microfracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery	9.5%-22%	-
Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery, canal adjacent stenosis	Mentioned but frequency not described	-
Non-union or pseudarthrosis, delayed union. Mal-union	4.62%-9,52%	-
Cessation of any potential growth of the operated portion of the spine	Mentioned but frequency not described	-
Loss of or increase in spinal mobility or function	Mentioned but frequency not described	-
Inability to perform the activities of daily living	Mentioned but frequency not described	-
Bone loss or decrease in bone density	Mentioned but frequency not described	-
Graft donor site complications including pain, fracture, or wound healing problems	Mentioned but frequency not described	-
Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise	0.62%-6.14%	-
Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise	0.45-1%	-
Reproduction system compromise, sterility, sexual dysfunction	1-1.54%	-
Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc	0.8%-13%	-
Change in mental status	Mentioned but frequency not described	-
Death	0.31-0.45%	2.27%
Infection	0%-34.6%	0.5%-2%
Technical issues - Early or late loosening of any or all of the components, - Disassembly, bending and/or breakage of any or all of the components (screw breakage))	11.7%-17.24% 1.6%-9.52%	3.6%-7%
Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, tumor formation and/or autoimmune disease	0.22%	-
Pressure on the skin from components parts with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain	Mentioned but frequency not described	20.45%

Tissue or nerve damage caused by improper positioning and placement of implants or instruments	Mentioned but frequency not described	-
Post-operative change in spinal curvature, loss of correction, height, and/or reduction	Mentioned but frequency not described	2.27%

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

Nonsurgical approaches :

Non-surgical options include drugs, physiotherapy, spinal injections, lifestyle modification, and multidisciplinary rehabilitation. It is generally admitted in the guidelines that these approaches should always be considered as first choice given the limited level of demonstration of the benefit of surgical technique on the long term. Conservative interventions also appear to reduce fear (especially fear of falls) amongs patients with low back pain.

Nevertheless, when all applicable non-surgical approaches have been tried and failed for at least several months, invasive approaches can be proposed, with a careful weighing of the benefit risk of the intervention for the patient.

Invasive / Surgical approaches

In the majority of cases, spinal disc herniation articular facets syndrome doesn't require surgery. Surgery may be useful in those with a herniated disc that is causing pain and neurological symptoms in the lower limbs. (NASS guidelines). If there is incontinence, weakness and genital numbness (Cauda Equina syndrome) it is considered a medical emergency requiring immediate attention and possibly surgical decompression.

Several techniques are described in the literature:

- **Discectomy** (removal some or all of a damaged disc, which can be helpful if it's pressing on a nerve).
- **Fusion surgery** (in case of a severely damaged disc, it may be removed. To re-stabilize this part of the spine, the surrounding vertebrae are fused (permanently joined) together).
- **Artificial disc replacement** (The damaged disc is removed and replaced with an artificial, or prosthetic, disc.)

7. SUGGESTED PROFILE AND TRAINING FOR USERS

BDyn implants are devices intended to be used by a qualified surgeon with knowledge in anatomy and spine surgery. No specific training is required from the patients.