Summary of safety and clinical performance (SSCP)
Screw-Rod-Family
MONOPOLY / CONKLUSION / DIPLOMAT /COSY

Revision 3

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Manufacturer´s reference number for SSCP

SSCP 003 Screw_Rod Family

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Purpose

This document provides a summary of safety and clinical performance on the screw / rod systems, namely MONOPOLY, DIPLOMAT, CONKLUSION and COSY by SIGNUS Medizintechnik GmbH.

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.

This SSCP contains information for users/healthcare professionals and patients. Therefore, the SSCP has two parts: In part 1, information is given for healthcare professionals. In the second part, the same information is given for patients not expected to have any background medical knowledge..

Change history

Version	Author	Date	History description	Revision validated by the Notified Body
0	Dr. Georg Lambert	25.11.2022	Preparation of first draft version for evaluation by the Notified Body. The evaluation will be based on the English version. The SSCP will be finalized after positive evaluation of the draft by the Notified Body.	☐ Yes Validation language: English ☒ No
1	Dr. Georg Lambert	05.03.2024	Update of the draft according to NB deviation report.	☐ Yes Validation language: English ☒ No
2	Dr. rer. nat. Stefan Schumacher	05.12.2025	Update of the draft according to the current CER and NB deviation reports to SSCPs of other systerms .	☐ Yes Validation language: English ☒ No
3	Dr. rer. nat. Stefan Schumacher	20.01.2026	Update of the draft according to NB deviation report. Creation of final document.	☒ Yes Validation language: English ☐ No

Part 1: Medical professionals

The first chapter of this part contains regulatory information about the device, the manufacturer and the notified body. The second chapter provides information about the intended use as well as indications and contraindications. The device and its application are described in the third sub-chapter.

Details on the exact device dimensions can be found in the tables below.Update of the draft according to the current CER.

Details on the exact device dimensions can be found in the tables below.

1 Device desciption

1.1 Overview of implants

There are previous generation.

Note on previous generations and changes:

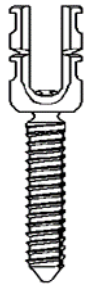
- COSY is based on the screw-rod system GIBRALT (no longer on the market) that was developed, manufactured and certified by another manufacturer and acquired by SIGNUS. SIGNUS let the system be certified as COSY under MDD including some technical modifications and optimizations for better commercialization. Further modifications that are now part of the MDR certification were made after MDD certification. These modifications include e.g. cannulation of screws, angulation of screws/tulips, simplification of saddle design, angular flexibility of rods, lengths of pedicle screws, and occipital plate sizes. Any modifications have been evaluated and determined to have no impact on safety or performance, as substantiated by bench testing data. Through assessment of technological characteristics, indications for use and performance data, it has been demonstrated that those design changes do not change the fundamental function of the system, and that no changes in clinical results are to be expected.

- After MDD certification of DIPLOMAT, "fast tip" versions of the screws were added to the portfolio with a design change that gives the screws an immediate "bite" in the bone; it has been demonstrated that the performance of the modified screw will be identical to previous ones, and that the design adaptations of the screw shafts are sufficiently covered by the mechanical characterization of the pedicle screw and by the similarity consideration. Furthermore, an additional length of an offset-connector was added without further design changes.

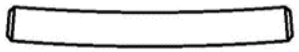
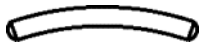
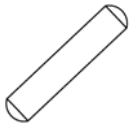
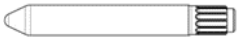
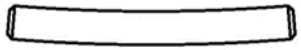
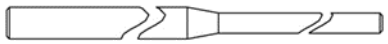
- The original MONOPOLY I system with set screws with very fine thread has been replaced by MONOPOLY II with set screws with bigger threads. Apart from that, the system remains unchanged.

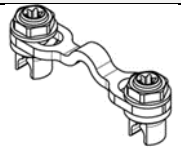
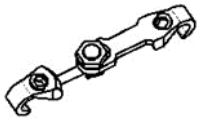
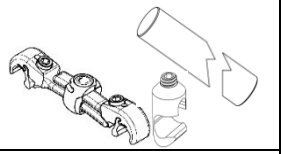
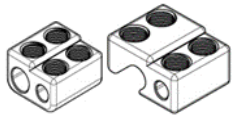
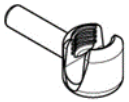
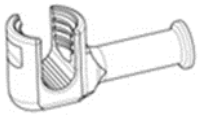
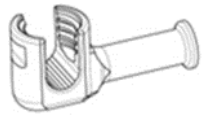
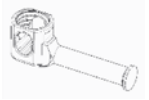
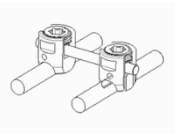
Table 1: Overview on screw rod implants.

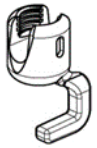
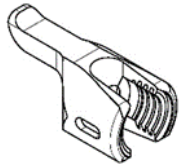
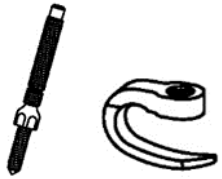
Product Group			Material	Sample image			
				Cervical	lumbar		
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Screws	Pedicle screw monoaxial	Standard	TiAl6V4 ELI acc. to ASTM F136	N/A			
		Reduction		N/A	N/A		

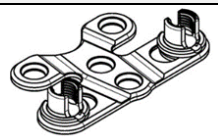
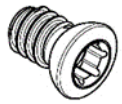
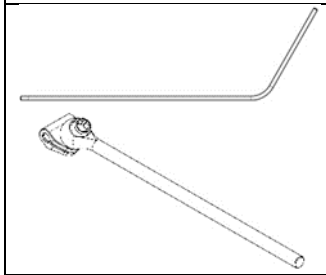
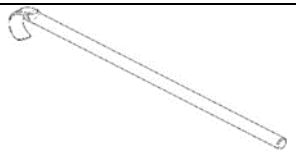
Product Group			Material	Sample image			
				Cervical	lumbar		
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Screws	Pedicle screw polyaxial	Standard	TiAl6V4 ELI acc. to ASTM F136		N/A		
		Reduction		N/A	N/A		
		Percutaneous		N/A	N/A	N/A	

Product Group			Material	Sample image			
				Cervical	lumbar		
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Screws	Other screws	Locking cap	TiAl6V4				
Additional components		i.e. Tulips		N/A		N/A	

Product Group			Material	Sample image			
				Cervical	lumbar		
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Rods	open	curved	TiAl6V4 ELI acc. to ASTM F136			N/A	
		straight				N/A	
	MIS	MIS curved	TiAl6V4 ELI acc. to ASTM F136	N/A	N/A		
		MIS straight		N/A	N/A		
	CoCr	curved; Cobalt Chrom	CoCrMo-alloy nach ASTM F1537		N/A	N/A	N/A
		straight; Cobalt Chrom			N/A	N/A	
	Hybrid	straight; Titan Hybrid	TiAl6V4 ELI		N/A	N/A	N/A

Product Group			Material	Sample image			
				Cervical		lumbar	
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Connectors		Cross connector	TiAl6V4 ELI nach ASTM F136		N/A		
		Inline Connector			N/A	N/A	N/A
		Parallel connector			N/A		
		Offset connector open			N/A		
		Offset connector closed		N/A	N/A	N/A	
		Cross connector tulips		N/A	N/A	N/A	

Product Group			Material	Sample image			
				Cervical	lumbar		
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Hooks		Hook	TiAl6V4 ELI acc. to ASTM F136		N/A	N/A	N/A
		Offsethook			N/A	N/A	N/A
		Laminahook				N/A	

Product Group			Material	Sample image			
				Cervical		lumbar	
				COSY	CONKLUSION	MONOPOLY	DIPLOMAT
Special parts	Occiput-Plate	Occiput Plate	TiAl6V4 ELI nach ASTM F136		N/A	N/A	N/A
		Occipital Screw			N/A	N/A	N/A
		Occipital Rod			N/A	N/A	N/A
		Locking Cap			N/A	N/A	N/A
		Atlas Hook			N/A	N/A	N/A

1.2 Thoracolumbar systems

The systems consist of a range of rods, polyaxial and monoaxial screws, offset and parallel connectors, cross connectors, lamina hooks and lamina screws. These components are used in a variety of configurations, with each construct being customized for the individual patient.
The systems are used in one or more segments. The aim is stabilization until bony fusion of the spine has taken place. The implants are implanted using instruments specifically developed for this purpose.
The DIPLOMAT screws are available as one- or two-piece implants. Depending on the indication and surgical situation, the polyaxial screws can be individually combined with the separately available standard, reduction, and MIS tulips. The tulip can be exchanged in-situ if required. MONOPOLY and CONKLUSION screws are not modular and are only available as one-piece implants. Monoaxial screws are available as one-piece implants.
DIPLOMAT and MONOPOLY can be used openly, percutaneously, or minimally invasively (MONOPOLY MIS using the NEVIO instruments). CONKLUSION is only used openly.
For the treatment of spinal deformities, the DIPLOMAT Deformity System can be used as a hybrid system (hooks and pedicle screws) or as a stand-alone system (hooks only). DIPLOMAT Deformity is a hook-based system for use on the thoracic / lumbar spine (TH2 - L5).
Cannulated and fenestrated screws (from Ø 5.5 mm) are available for DIPLOMAT and MONOPOLY, through which cement can be injected if required (insufficient bone quality).
CONKLUSION is only available in solid (not cannulated and not fenestrated) design. Further system-related information on the surgical method can be found in the respective product information.

Product family	**Product variants**	**Instruments**
MONOPOLY	MONOPOLY	MONOPOLY
	MONOPOLY MIS	NEVIO
DIPLOMAT	DIPLOMAT Open	DIPLOMAT Basic Set
	DIPLOMAT MIS	DIPOLMAT Basic Set + MIS Extension Set
	DIPLOMAT Deformity	DIPLOMAT Deformity + DIPLOMAT Basic Set
CONKLUSION	CONKLUSION	CONKLUSION

DIPLOMAT and DIPLOMAT Deformity (LSZ)

The DIPLOMAT pedicle screw system is a modular rod-screw system that connects two or more screws via the screw head and a rod using a force-fit or form-fit connection (Figure 1, Figure 2). Additional fixation elements, such as cross bars, hooks, connectors and washers, can also be used. The DIPLOMAT pedicle screw system is applied to provide internal posterior stabilization until bone fusion in the lumbar or thoracic spine has taken place. The pedicle screw system is implanted by a posterior approach. The implant is screwed into the vertebral body via the pedicle. It can be applied as single segment or multiple segment construct. Implantation is facilitated by use of specially developed instruments for inserting and positioning the implants. Only these instruments ensure safe use. This range, as well as the different types of screws, tulips and other instruments can be found in the product information. The augmentable DIPLOMAT pedicle screw system can be optionally used with cement for improved anchorage in bone that is of lower density (osteoporosis). The DIPLOMAT implants are suitable for open as well as minimally invasive surgery (MIS). The implants generally consist of two pieces, the screw itself and the tulip (Figure 2). The tulip is available in three different types: standard, percutaneous and as a reduction tulip. The screws are designed as self-tapping with a double thread and a displacement of 4,5 mm per turn. The DIPLOMAT pedicle screws are available in the following diameters: 4,5mm, 5,5mm, 6,5mm, 7,5mm, 8,5m and 9,5mm. The length (depending on the diameter) differs from 30 to 100 mm. Details can be found in the respective product information brochures.

The SIGNUS DIPLOMAT Deformity system is a lamina hook-based system. It can be used as a stand-alone system by using only laminar hooks (DIPLOMAT Deformity (LSZ) or as a hybrid system which consists of laminar hooks and additional use of pedicle screws (DIPLOMAT) in the same procedure.

The DIPLOMAT Deformity system offers a variety of different sized infralaminar hooks. Once the hook has been placed, it is secured in position with a lamina screw. The lamina screw prevents the hook from slipping. Correction is performed once all hooks have been placed. The hooks are connected to the longitudinal rod by a clip mounted on the threaded post of the lamina screw. The clip's position on the threaded post is controlled by a shear nut. This construct allows gradual reduction of the rod to the hook.

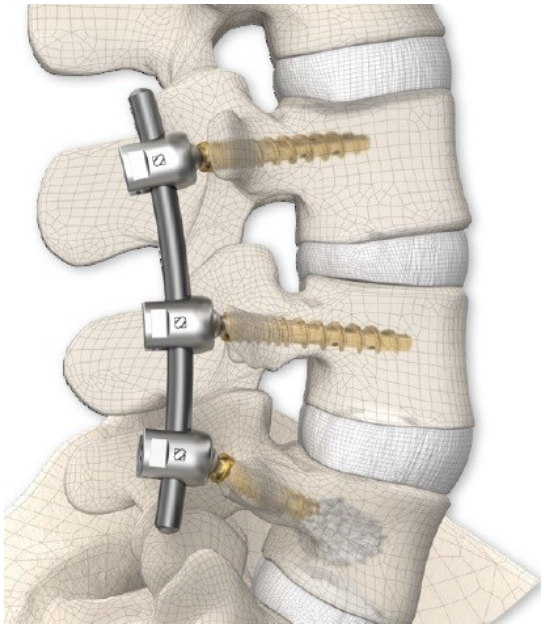


Figure 1: DIPLOMAT Construct

Figure 2: DIPLOMAT Screw

The following figure shows an example of the instrument tray from DIPLOMAT BASIC AC10AZ and AC10AY:

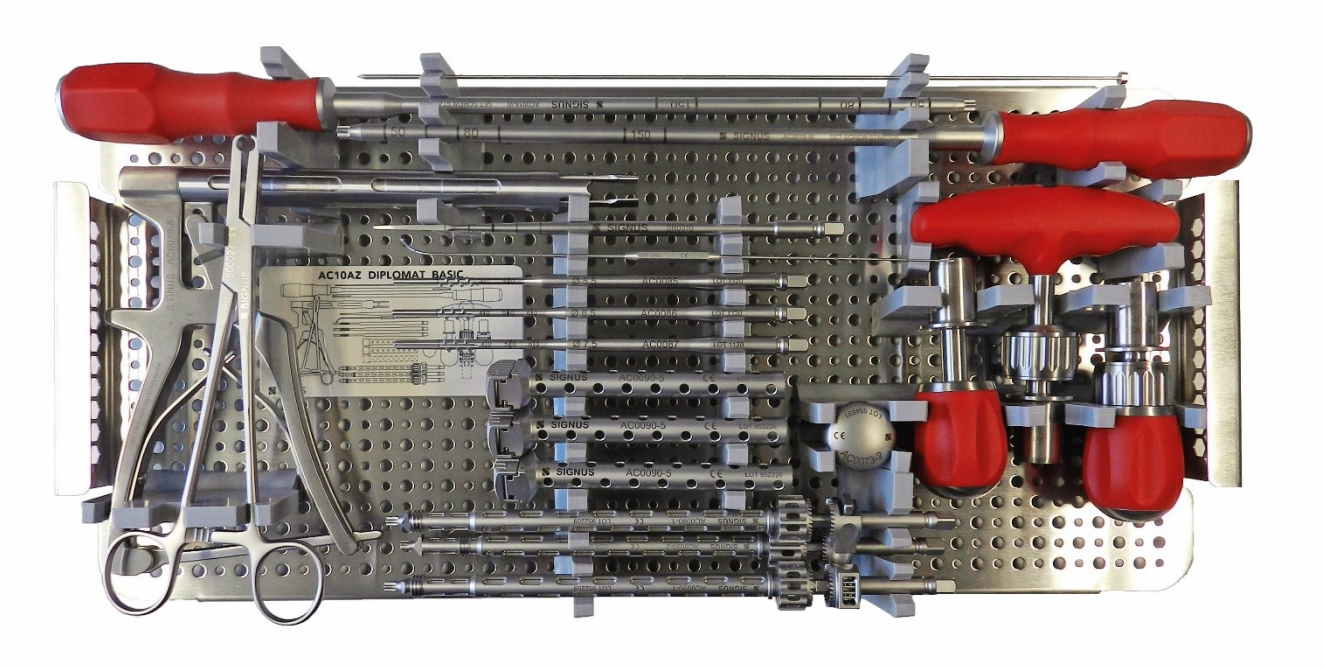


Figure 3: AC10AZ DIPLOMAT BASIC

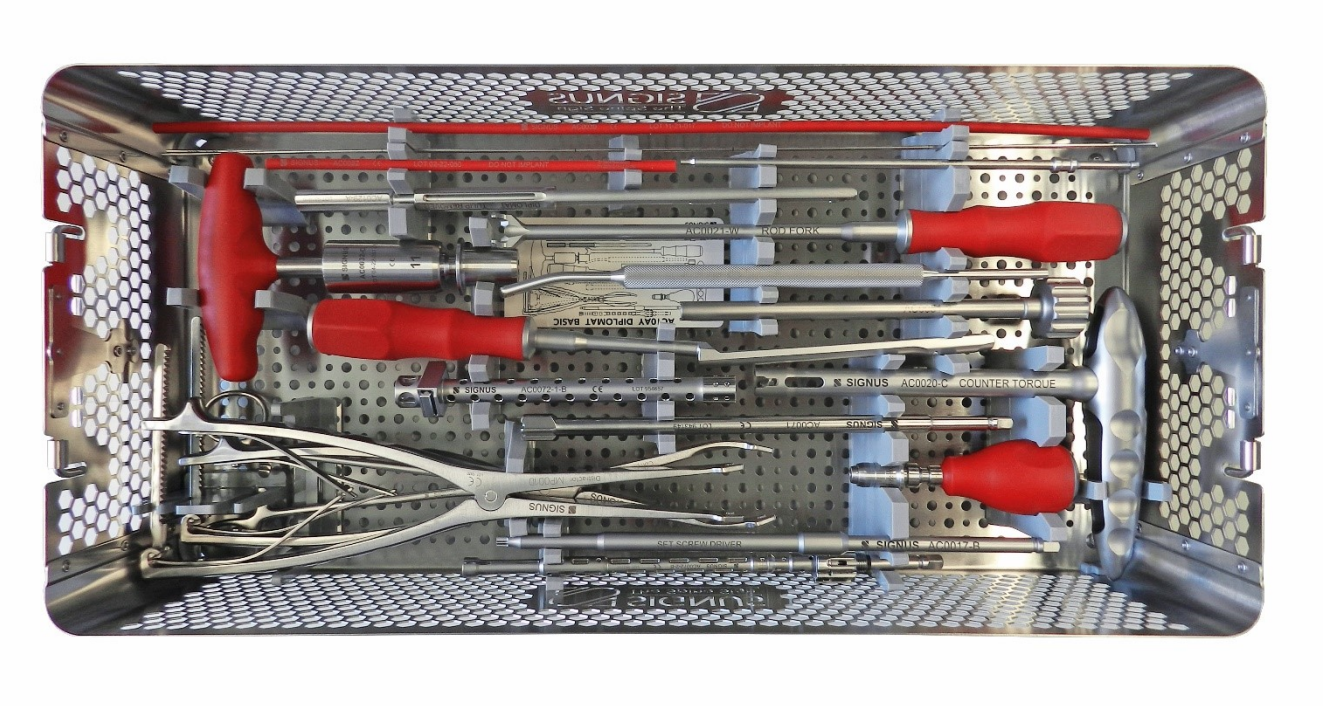


Figure 4: AC10AY DIPLOMAT BASIC

Table 2: Screw sizes and increments DIPLOMAT

	Diameter (mm)	**Length (mm)**	**Additional information**
Pedicle screw without tulip; polyaxial	4.5	30-60; increment 5	Available as sterile and non-sterile implant
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	35-65; increment 5	
	8.5	40-70; increment 5	
	9.5	40-70; increment 5	
Pedicle screw without tulip; polyaxial. Cannulated	4.5	25-60; increment 5	Available as sterile and non-sterile implant
	5.5	25	
	6.5	25	
	7.5	25	
	8.5	25	
	9.5	25	
Pedicle screw without tulip; polyaxial. Cannulated, fenestrated	5.5	30-60; increment 5	FT version available*
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
	8.5	30-80; increment 5 80-100; increment 10	
	9.5	30-80; increment 5 80-100; increment 10	
Pedicle screw cannulated monoaxial	4.5	30-60; increment 5	
Pedicle screw cannulated monoaxial, with long sleeves for reduction	4.5	30-60; increment 5	
Pedicle screw cannulated monoaxial, augmentable	5.5	30-60; increment 5	FT version available*
	6.5	30-65; increment 5	
	7.5	35-80; increment 5 80-100; increment 10	
	8.5	40-80; increment 5	

	Diameter (mm)	**Length (mm)**	**Additional information**
		80-100; increment 10	
	9.5	40-80; increment 5 80-100; increment 10	
Pedicle screw cannulated monoaxial, augmentable, with long sleeves for reduction, augmentable	5.5	30-60; increment 5	FT version available*
	6.5	30-65; increment 5	
	7.5	35-80; increment 5 80-100; increment 10	
	8.5	40-80; increment 5 80-100; increment 10	
	9.5	40-80; increment 5 80-100; increment 10	
FT (fast tip) refers to a modified threat geometry allowing a faster insertion of the implant.			
Diplomat deformity			
Lamina Screw	5 – 10 (increment 2.5)		
Lamina Hook	5 – 10 (increment 2.5)		

MONOPOLY

The pedicle screw system MONOPOLY is a rod-screw system that connects two or more screws via the screw head and a rod in a force-fit or form-fit connection (Figure 5). Additional fixation elements, such as cross bars, hooks, connectors and washers, can also be used. The MONOPOLY pedicle screw system is applied to provide internal posterior stabilization until bone fusion in the lumbar or thoracic spine has taken place. The pedicle screw system is implanted by a posterior approach. The implant is screwed into the vertebral body via the pedicle. It can be applied as single segment or multiple segment construct. Implantation is facilitated by use of the specially developed instruments for inserting and positioning the implants. Only these instruments ensure safe use. The screw placement is guided by a Bonewire. The MONOPOLY pedicle screws are available as monoaxial or polyaxial screws. The MONOPOLY implants are also suitable for minimally invasive surgery (MIS). MONOPOLY II FS screws are fenestrated in the distal third allowing cement injection into the vertebral body in case of reduced bone quality. NEVIO is a part of the MONOPOLY system with additional rods and some instruments specially designed for MIS application.

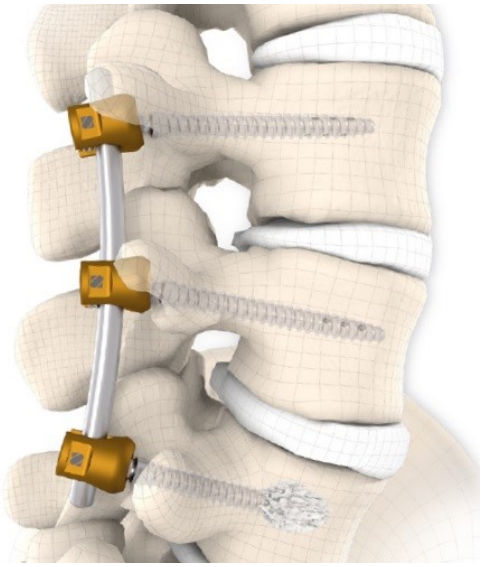


Figure 5: MONOPOLY Construct

Table 3: Screw sizes and increments Monopoly

	Diameter (mm)	**Length (mm)**	**Additional information**
Pedicle screw Monoaxial	4.5	30-55; increment 5	
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
	8.5	35-80; increment 5 80-100; increment 10	
Pedicle screw polyaxial	4.5	30-55; increment 5	
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
Pedicle screw Monoaxial Reduction (long tulip)	4.5	30-55; increment 5	
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
	8.5	35-80; increment 5 80-100; increment 10	
Pedicle screw Polyaxial Reduction (long tulip)	4.5	30-55; increment 5	
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
VC Pedicle screw cannulated monoaxial	4.5	30-55; increment 5	"VC" stands for "versus cannulated" and means that the screws are available in a cannulated version
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
	8.5	35-80; increment 5	

	Diameter (mm)	Length (mm)	Additional information
		80-100; increment 10	
VC Pedicle screw cannulated polyaxial	4.5	30-55; increment 5	"VC" stands for "versus cannulated" and means that the screws are available in a cannulated version
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
VC Pedicle screw cannulated monoaxial Reduction (long tulip)	4.5	30-55; increment 5	"VC" stands for "versus cannulated" and means that the screws are available in a cannulated version
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	
	8.5	35-80; increment 5 80-100; increment 10	
VC Pedicle screw cannulated polyaxial Reduction (long tulip)	4.5	30-55; increment 5	"VC" stands for "versus cannulated" and means that the screws are available in a cannulated version
	5.5	30-60; increment 5	
	6.5	30-65; increment 5	
	7.5	30-80; increment 5 80-100; increment 10	

CONKLUSION

The pedicle screw system CONKLUSION is a rod-screw system that connects two or more screws via the screw head and a rod in a force-fit or form-fit connection (Figure 6) Additional fixation elements, such as cross bars, hooks, connectors and washers, can also be used. The pedicle screw system is applied to provide internal posterior stabilization until bone fusion in the lumbar or thoracic spine has taken place. The pedicle screw system is implanted by a posterior approach. The implant is screwed into the vertebral body via the pedicle. It can be applied as single segment or multiple segment construct. Implantation is facilitated by use of the specially developed instruments for inserting and positioning the implants. Only these instruments ensure safe use.

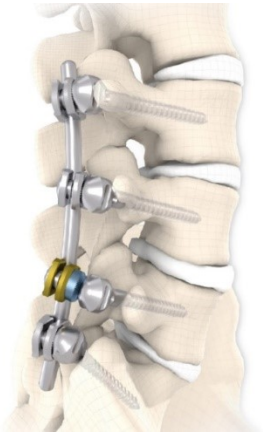


Figure 6: CONKLUSION Construct

Table 4: Screw / hook sizes and increments CONKLUSION. Implants are available as sterile and non-sterile version.

	Diameter (mm)	**Length (mm)**
Pedicle screw	4.3	30-40; increment 5
	5.3	35-60; increment 5
	6.5	35-70; increment 5
	7.5	35-70; increment 5
	9.0	45-80; increment 5 80-100; increment 10
Lamina hook		6 and 8 mm
Infralaminar hook		6 and 8 mm
Supralaminar hook		6 and 8 mm

1.3 Cervical system (COSY)

The implants are available in different lengths, diameters and sizes to adapt to the patient's anatomy. The decision to remove an implant is the responsibility of the attending physician.

The system consists of rods, hooks, polyaxial screws, fixation screws, connectors, occipital plates and occipital screws in different designs and sizes, which can be firmly connected to a rod in various configurations. The system includes hybrid rods in diameters from 3.5 mm to 5.5 or 6.0 mm and parallel rod-to-rod connectors that allow 3.5 mm rods to be connected to 5.5 or 6.0 mm rods. These components are designed to allow the connection of the COSY cervicothoracic occipital rod screw system to a thoracolumbosacral pedicle screw system (DIPLOMAT, DIPLOMAT Deformity, MONOPOLY). The implants are made of a titanium alloy (TiAl6V4). Rods are available in titanium alloy or cobalt chrome versions.

Implantation is facilitated by the use of specially developed accessories for inserting and positioning the implant. Only these accessories guarantee safe use. The respective product information provides further system-related information on the surgical procedure.

The respective product information provides further system-related information on the surgical procedure.

The COSY spine system, formerly marketed under the name GIBRALT, is a posterior system used for surgical immobilization, stabilization, fixation and correction of malpositions of the human cervical spine and the cervicothoracic transition, if necessary, including the occipital-cervical transition (Figure 7).

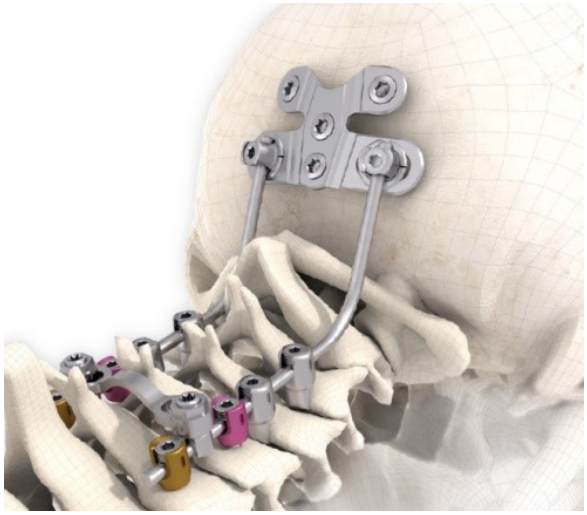


Figure 7: COSY Construct

The system was acquired by SIGNUS. The original name of the device was GIBRALT. The GIBRALT system was mainly marketed in the US and clinical data is available for the system. COSY was approved and placed on the market by SIGNUS under MDD.
The system consists of rods (Ø3.5mm x length: 30,40,50,60,70,80 and 90mm curved and 80,120,240 and 360mm straight), hooks, occiput plate, polyaxial screws (Polyaxial Up to 35° angulation (total 70°) Ø3.5mm & Ø4.0mm and Ø4.5mm. Polyaxial Shank screws Up to 35° angulation (total 70°) Ø3.5mm & Ø4.0mm), fixation screws, occipital screws and connectors

in various sizes (Head to head: 22mm-28mm,22- 30mm, 26mm- 36mm, 28mm- 34mm, 32mm- 42mm, 34mm- 40mm, 40-46 mm, 44mm-52mm, 46mm-52mm; see overall product list for details), which can be connected to the rod or to an occiput plate in various configurations. Occipital rod has a diameter of Ø3.5mm and is pre-angled by 120° (or alternatively an adjustable rod is available for better anatomical adaptation to the occiput). Specific instruments for the system are available. The components of the COSY spinal system are made of a titanium alloy. Rods are available in titanium alloy and cobalt-chrome alloy versions. This system can be used independently or in conjunction with other SIGNUS Screw-Rod-Systems (e.g.: DIPLOMAT, DIPLOMAT Deformity and MONOPOLY).

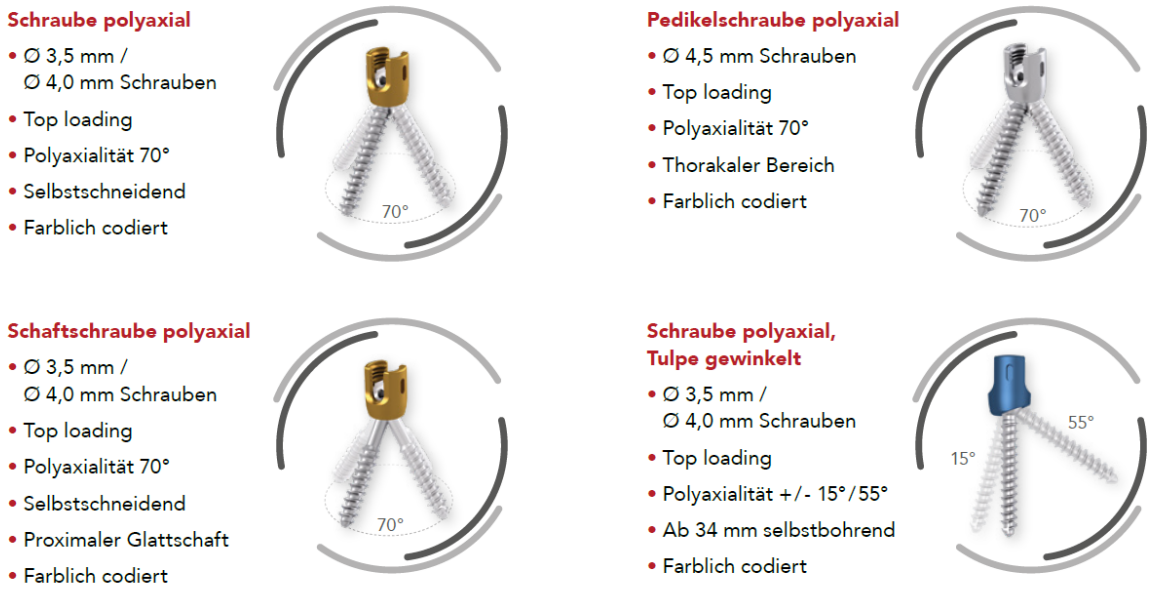


Figure 8: COSY Screw options

Table 5: Implant sizes and increments Cosy. All implants are available in sterile and non-sterile version.

	Diameter (mm) / holes	**Length (mm)**
Occiput plates	4 and 5 holes	
Occipital screws	4.5	6-16 mm; increment 2
Screws with Tulip, cannulated, polyaxial	3.5	8 - 40; increment 2
	4.0	8 - 40; increment 2
Pedicle Screws with Tulip, cannulated, polyaxial	4.5	20 – 50; increment 5
Shank -Screws with Tulip, cannulated, polyaxial	3.5	20-46; increment 2
	4.0	20-46; increment 2

Screw with tulip angled polyaxial, selfdrilling	3.5	34-50; increment 2
	4.0	34-50; increment 2
Screw with tulip angled polyaxial	3.5	20-32; increment 2
	4.0	20-32; increment 2
Screw with tulip angled cannulated polyaxial, selfdrilling	3.5	34-50; increment 2
	4.0	34-50; increment 2
Screw with tulip angled cannulated polyaxial	3.5	20-32; increment 2
	4.0	20-32; increment 2
Screw with tulip polyaxial	3.5	8 - 40; increment 2
	4.0	8 - 40; increment 2
Pedicle screw with tulip polyaxial	4.5	20 – 50; increment 5
Shank screw with tulip polyaxial	3.5	20-46; increment 2
	4.0	20-46; increment 2

Change history of COSY

The COSY spine system was acquired by SIGNUS. The original name of the device was GIBRALT. The GIBRALT system was mainly marketed in the US and clinical data is available for the system. COSY was approved by SIGNUS under MDD.

The COSY system was technically modified (see also 1.1). These modifications have been evaluated to neither have an impact on safety or performance, nor to change the intended purpose of the system.

COSY and GIBRALT demonstrate equivalence. The COSY system received clearance through the FDA 510(k) process, with GIBRALT serving as its equivalent or predicate device. Both systems have been approved under the 510(k) FDA regulations.

1.4 Generalities

Table 6: Administrative particulars (Section A-MDCG 2020-13)

Aspect	Description
Basic UDI-DI	DIPLOMAT: 040784401050081041146 DIPLOMAT steril: 040784401050081042149 DIPLOMAT CoCr: 04078440105008204114H DIPLOMAT CoCr steril: 04078440105008204214L DIPLOMAT Deformity*: 04078440105008105114B DIPLOMAT Deformity steril*: 04078440105008105214E CONKLUSION: 04078440105005104112X CONKLUSION steril: 040784401050051042132 CONKLUSION Haken*: 040784401050051051134 CONKLUSION Haken steril*: 040784401050051052137 MONOPOLY: 040784401050141041133 COSY: 04078440105029104115M COSY steril: 04078440105029104215Q COSY CoCr: 04078440105029204115Y COSY CoCr steril: 040784401050292042163 COSY Haken*: 04078440105029105115S COSY Haken steril*: 04078440105029105215V
Medical device name	CONKLUSION CONKLUSION Haken DIPLOMAT DIPLOMAT Haken DIPLOMAT DEFORMITY MONOPOLY COSY COSY Haken
Product- Family	Screw-Rod-System
Certificate Number	Not assigned
Project Number	CER 003
Risk Class according to Regulation (EU) 2017/745 (MDR):	Class IIb, Class III* Classification in accordance with MDR Annex VIII, rule 8,indent 9 *Classification in accordance to MDCG Guidance 2021-24 (valid for hooks that fix the rod on the spinal column)
Applicable code(s) per Commission implementing Regulation (EU) 2017/2185	MDN1102 Bones and skeletal implants MDN1208 Instruments
Manufacturer(s) name and SRN:	SIGNUS Medizintechnik GmbH Industriestr. 2 63755 Alzenau DE-MF-000006200
Authorized representative (if applicable) name and	not applicable

SRN:	
Notified body:	mdc medical device certification GmbH
Notified body number:	0483
E-mail contact of NB:	mdc@mdc-ce.de
Telephone contact of NB:	+49 711 253597-0
Duration	Implants: ≥ 30 days Instruments: < 60 Min
Invasive Device	yes
Body contact	Direct
Usage	Implant: Single-use device Instruments: Reusable device and Single-use device
Sterile	yes
Radioactivity	no
Active Medical Device	no
Software	not applicable
Medicinal substance	No
Biological Material	No

In which countries is the device currently on the market? Since when? How many devices are on the market?	CONKLUSION in EU: Since 2003 (first CE-marked) CONKLUSION in USA: Since 2003 CONKLUSION in Mexico: Since 2008 Total amount of CONKLUSION implants sold until 12/2024: 90.657 (worldwide) COSY in EU: Since 2021 (first CE-marked) COSY in USA: Since 2022 (FDA registration) COSY in Australia: Since 2024 Total amount of COSY implants placed on the market until 10/2025: 4.302 DIPLOMAT in EU: Since 2014 (first CE-marked) DIPLOMAT in Australia: Since 2015 DIPLOMAT in USA: Since 2016 DIPLOMAT in Mexico: Since 2020 DIPLOMAT in UK: Since 2014 DIPLOMAT in Malaysia: Since 2019 DIPLOMAT in Thailand: Since 2020 Total amount of DIPLOMAT implants sold until 12/2024: 459.521 (worldwide) DIPLOMAT Deformity – LSZ in EU: Since 2011 (first CE-marked) DIPLOMAT Deformity – LSZ in Australia: Since 2013 DIPLOMAT Deformity – LSZ in Russia: Since 2017 DIPLOMAT Deformity – LSZ in Thailand: Since 2020 Total amount of DIPLOMAT Deformity – LSZ implants sold until 12/2024: 14.354 (worldwide) MONOPOLY in EU: Since 2007 (first CE-marked) MONOPOLY in Australia: Since 2013 MONOPOLY in USA: Since 2008 MONOPOLY in Mexico: Since 2008 MONOPOLY in Vietnam: Since 2015 MONOPOLY in Brasilien: Since 2020 MONOPOLY in Ecuador: Since 2016 MONOPOLY in Colombia: Since 2013 Total amount of MONOPOLY implants sold until 12/2024: 259.004 (worldwide)
For Class III and Class IIb devices	
Medical Area(s)	**Associated competence-related areas**
Orthopaedics, traumatology, rehabilitation, rheumatology	☐ Joint replacements (hip, knee, shoulder)
	☒ Spinal devices
	☐ Non-articulating devices, rehabilitation
	☐ Other
Circulatory system: cardiovascular /	☐ Prosthetic heart valves and devices for heart valve repair
	☐ Cardiovascular stents (metallic and bioresorbable) and vascular

lymphatic system	prostheses
	☐ Active implantable cardiac devices and electrophysiological devices
	☐ Structural interventions and new devices (e.g. LAA/PFO occluders, heart failure devices)
	☐ Cardiac surgery including extracorporeal membrane oxygenation, cardiopulmonary bypass devices, artificial hearts (and left ventricular assist devices)
	☐ Other
Respiratory, anaesthesiology, intensive care	☐ Respiratory and anaesthetic devices
Neurology	☐ Central and peripheral nervous system devices
	☐ Implants for hearing and vision (sensory recovery)
	☐ Neurosurgical devices
	Other
Endocrinology and diabetes	☐ Endocrinology and diabetes (e.g. insulin delivery systems and closed-loop systems, continuous glucose monitoring) Implantable systems
General and plastic surgery, dentistry	☐ Surgical implants and general surgery
	☐ Plastic surgery and wound care
	☐ Maxillofacial surgery
	☐ Dentistry (devices for dentistry (oral surgery, implantology, dental materials incl.))
	☐ Other
Obstetrics & gynaecology including reproductive medicine	☐ Devices for obstetrics and gynaecology
Gastroenterology & hepatology	☐ Devices for gastroenterology and hepatology
Nephrology & urology	☐ Devices for nephrology and urology
Ophthalmology	☐ Devices for ophthalmology

Table 7: EMDN codes

Nr.	Description	System
P09070301	PROSTHESES, CERVICAL FIXATION SYSTEMS	COSY
P09070302	THORACOLUMBOSACRAL SPINE, FIXATION SYSTEMS	DIPLOMAT, MONOPOLY, CONCLUSION

1.5 Intended purpose

DIPLOMAT, MONOPOLY and CONKLUSION are screw fixation systems used for dorsal surgical stabilisation / fixation and correction of the human thoracic and lumbar spine, including the sacrum (TH2 - S2) if necessary.

DIPLOMAT Deformity is a hook fixation system used for dorsal surgical stabilisation / fixation and correction of the human thoracic and lumbar spine (TH2 - L5).

The COSY cervicothoracic occipital rod screw system is a system for use in the cervical spine. The implants are used for the surgical immobilisation, stabilisation and correction of malpositions of the human cervical spine (C1-C7) and the cervicothoracic junction (TH1-TH3), as well as the occipitocervical junction, if necessary.

Implant-specific instruments developed by SIGNUS are available for use of the implant system. The insertion of the implants has been developed and tested only with SIGNUS' own instruments.

1.6 Intended patient population and medical conditions to be diagnosed, treated and/or monitored

COSY, MONOPOLY, CONKLUSION, DIPLOMAT and DIPLOMAT Deformity are intended for use in skeletally mature patients. In addition, constructs of the systems DIPLOMAT and DIPLOMAT-Deformity based on screws with diameters of 4.5 - 6.5 mm and lengths of 25 - 60 mm, as well as lamina hooks with lamina screws (lengths of 5.5 to 7.5 mm) are also indicated for pediatric applications without age limitation. The texts are copied from the IFU.

1.7 Indications MONOPOLY, CONKLUSION, DIPLOMAT, and DIPLOMAT Deformity

MONOPOLY, CONKLUSION and DIPLOMAT are intended for stabilization / fusion of the thoracic / lumbar and sacral spine (TH2 - S2) and DIPLOMAT Deformity for stabilization / fusion of the thoracic / lumbar spine (TH2 - L5), for the following indications: Degenerative disc disease:

- Degenerative disc disease (e.g. disc prolapse, instabilities, spondylosis)
- Spondylolisthesis
- Trauma (e.g. fractures, dislocations)
- Spinal canal stenosis

- Deformities and malpositions (e.g. scoliosis, hyperkyphosis, hyperlordosis)
- Tumors
- Pseudarthrosis and / or failed previous fusion

In the presence of reduced bone quality, the use of cement augmentation should be considered.

1.8 Indications COSY

The COSY Cervicothoracic - Occipital Rod-Screw System is used to immobilize and stabilize spinal segments as a supplement to fusion in the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 - C7) and the thoracic spine (TH1 - TH3):

- Traumatic spinal fractures and / or traumatic dislocations
- Instabilities or deformities
- Failed previous fusions (e.g. pseudoarthrosis)
- Tumors involving the cervical spine
- Degenerative diseases including persistent radiculopathy and / or myelopathy
- Neck and / or arm pain of discogenic origin, confirmed by radiographic examinations
- Degenerative disease of the facets with instability
- Spinal stenosis

The COSY cervicothoracic-occipital rod-screw system is designed to restore spinal stability equally, even without fusion, for a limited period of time in patients with advanced-stage cervical spine tumors where life expectancy is so short that fusion is no longer possible.
To achieve an additional level of fixation, the COSY Cervicothoracic - Occipital Rod-Screw System can be connected to the DIPLOMAT, DIPLOMAT Deformity and MONOPOLY systems using rod-to-rod connections or hybrid rods.

1.9 Intended user

The implants may only be inserted by a surgeon experienced in spine surgery.

1.10 Contraindications

1.10.1 MONOPOLY, CONKLUSION, DIPLOMAT, and DIPLOMAT Deformity

Any medical or surgical condition that would preclude the potential benefit of spinal implantation is a contraindication. The following conditions may reduce the chances of success and should be considered by the surgeon. This list is not exhaustive:

- Infectious processes in, on or adjacent to the spine
- Allergy or intolerance to implant material
- Medical conditions that could prevent the success of the implantation (e.g. obesity, mental illness, pregnancy, poor general condition of the patient, lack of patient cooperation, rapidly progressive arthropathy, bone absorption)

- Abnormal bone density (severe osteoporosis, osteopenia or osteomalacia) that prevents secure anchoring even after cement augmentation
- Patients with insufficient tissue coverage over the surgical site
- Cases not listed under indications

In order to achieve optimal results, no implant components of the DIPLOMAT, DIPLOMAT Deformity, MONOPOLY and CONKLUSION spinal systems may be used with components from other systems or manufacturers, unless this is expressly permitted in this or another SIGNUS document. (Text as listed in the IFU)

1.10.2 COSY

Any medical or surgical condition that would preclude the potential benefit of spinal implantation is a contraindication. The following conditions may reduce the chances of success and should be considered by the surgeon. This list is not exhaustive:

- Abnomal bone density, osteoporosis or osteomalacia that prevents stable anchoring of the implant
- Infectious processes in, on or in adjacent regions of the spine
- Allergy or intolerance to the implant material
- Conditions that preclude any potential benefit of spinal surgery (e.g. severe damage to bone structures at the implant site, severely distorted anatomy due to abnormalities)
- Conditions that could prevent the success of implantation (e.g. obesity, mental illness, pregnancy, poor general condition of the patient, lack of patient cooperation, rapidly progressive arthropathy, bone absorption)
- Patients with insufficient tissue coverage over the surgical site
- The use of other metals or components that are not part of the screw system is not permitted
- Cases not listed under indications

In order to achieve optimal results, no implant components of the COSY Cervicothoracic - Occipital Rod-Screw System may be used with components of other systems or manufacturers, unless this is expressly permitted in this or another SIGNUS document..

1.11 Warnings / Precautions

The spinal implants are intended for single use only and cannot be reused. Reuse can lead to infection and / or loss of function or even death of the patient.

- SIGNUS implants may only be inserted using the instruments intended for this purpose. If the implants are inserted using other instruments, the correct implantation is not guaranteed.
- The indication, selection and implantation are the responsibility of the physician performing the procedure, who must be experienced and trained in performing spinal interventions.
- Unless otherwise specified, SIGNUS products must not be directly connected to the materials / components of other systems.
- Check the implant for scratches and other obvious damage. A damaged implant must not be used.
- Due to potential damage, the implant must not be reinserted after removal from the site.
- When inserting the implant, particular attention must be paid to protecting the nerve structures and blood vessels, and increased force must be avoided.
- Repetitive bending weakens the rod. The rod must not be bent back and forth.
- It is essential that the SIGNUS torque limiter is used to fix the screw plugs in place.

- Aftercare and follow-up examinations must be individually tailored to the patient and defined by the attending physician. After the operation, the patient's physical activities should only be permitted to a very limited extent for an appropriate post-operative period. This applies in particular to lifting weights, twisting movements and any kind of sport. Falls or sudden jerky movements of the operated region should be avoided.

1.12 Risks associated with the use

General risks of a surgical procedure and complications that may occur during a spinal procedure are not listed in the instructions for use. Potential risks and complications associated with the implant that may require revision surgery are:

1.12.1 MONOPOLY, CONKLUSION , DIPLOMAT , and DIPLOMAT Deformity

- Pseudoarthrosis / lack of fusion
- Foreign body sensitivity, allergic or other local / systemic side effects with regard to the implant materials used
- Misplacement
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Pedicle fracture
- Pedicle / nerve root perforation
- Nerve root / spinal canal injury
- Injuries and vascular damage due to bone cement leakage (e.g. PMMA)
- Visceral injury / infection and deep wound infection
- Temporary paraparesis
- Wear, bending or breakage of implant components
- Screw loosening
- Pain or recurring pain
- Hernia of the nucleus pulposus, disc disruption or degeneration at, above or below the level of the surgical procedure
- Vascular lesion
- Bone loss or reduction in bone density, possibly caused by stress shielding
- Postoperative loss of correction or changes in spinal curvature.

These risks can result in injuries to the surrounding tissue, nerves and blood vessels in all degrees of severity, including death.

1.12.2 COSY

- Loosening and / or breakage (e.g. with absence or delayed fusion)
- Postoperative loss of correction or changes in spinal curvature.
- Pseudoarthrosis / lack of fusion
- Pressure of the components on the surrounding tissue in patients with insufficient tissue coverage

- Foreign body sensitivity, allergic or other local / systemic side effects with regard to the implant materials used
- Misplacement
- In rare cases, an epidural hematoma may form postoperatively in patients with coagulation disorders undergoing anticoagulant therapy.
- Vascular lesion
- Neural lesions with reversible or permanent neurological deficits or paralysis
- Infection
- Pedicle fracture
- Nerve root / spinal canal injury
- Wear, deformation or breakage of implant components
- Improper locking of the construction can cause the tulip and the rod to come loose
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis
- Bone loss or reduction in bone density, possibly caused by stress shielding
- Hernia of the nucleus pulposus, disc disruption or degeneration at, above or below the level of the surgical procedure
- Pain or recurring pain
- Pedicle / nerve root perforation

These risks can lead to injuries of all degrees of severity to the surrounding tissue, nerves and blood vessels, which in extreme cases can even lead to death.

1.12.3 Incidents of risks / complications to be expected

The incidents of complications / adverse events are highly dependent on the performed procedure. As pedicle screws are used as general fixation device a stratification of rates for each situation is not possible.
According to the analysis of the market feedback and scientific literature, no systematic failures or complications related to SIGNUS screw-rod-systems were observed. Thus, their safety is confirmed. Nevertheless, as described in the instruction for use and in this SSCP, residual risks from both the surgical procedure and the medical device remain.
In accordance with the "Summary of Safety and Clinical Performance MDCG 2019-9 v1 Quantitative data", we present the complications associated with clinical data that were proactively gathered through PMS measures for our devices.
The below numbers shall provide rough guidance of expected incident rates based on literature on screw-rod systems.

Implant breakage	Up to 10%
Implant loosening	Up to 25%
Revision rate	Up to 10%
Adjacent level disease in cervical fusion	Up to 10%
Total complication rate	3.3% - 21.1%
Intraoperative complication rates	2.5% - 23.9%
Postoperative complication rates	3.1% - 35.9%

For the SIGNUS screw-rod systems the following values in below table were found by analysis of surgeries accompanied by SIGNUS personnel, of complaints received from the market, and from expert opinions (see also 2.2.1) based on the sale volume >800 000 since approval date until 30.11.2025:

Complications	**%**
Implant breakage	0,003%** 0,008%***
Implant loosening or migration	0,004%** 10%***
Revision rate	11%* (including revisions of competitor products, where SIGNUS products were used as replacement). Therefore, the actual revision rate for SIGNUS products is ca. 5%. 3%*** 0.33%****
Adjacent level disease in cervical fusion	n. a. (COSY has not yet been implanted)
Total complication rate	Implant related 0.8%* Procedure related 1.1%*
Intraoperative complication rates	Implant related 0.4%* Procedure related 1.1%*
Postoperative complication rates	Implant related 0.4%*

*: Based on surgeries accompanied from 2018-11/2025. Calculation based on the total number of accompanied surgeries in the period (1118).
**: Based on complaints received from 2018-11/2025. Calculation based on the total number of sold implants in the period (~500.000)
***: Expert opinion on CONKLUSION, 2003-2021, 1800 patients.
****: Expert opinion on DIPLOMAT (2020), 2015-2020, 600 patients

1.13 Clinical Benefit

In brief, the clinical benefit of the implants depends on the pathology leading to the surgery. There are different outcome measurements for clinical success such as pain reduction (often measured as VAS) or disability (often given as ODI).
To specify the clinical benefit of the implant in contrast to the clinical benefit of the entire procedure we use parameters such as fusion rate, implant stability and revision rate as the main indicators for clinical benefit.
The aim of the Screw-Rod Systems is to stabilize spinal segments. If this stabilization is achieved and maintained and allows fusion, this contributes to the clinical benefit independent of the underlying pathology treated.
A surgery can be unsuccessful even if these factors are fulfilled. However, in this case it is not relevant for safety assessment for the implant but for the surgical method.

1.14 Material composition

The implants MONOPOLY, CONKLUSION, DIPLOMAT and COSY are made from the following materials:

- Titanium alloy (TiAl6V4) according to ASTM F 136 / ISO 5832-3
- Cobalt-chromium-molybdenum alloy according to ASTM F 1537 / ISO 5832-12

Composition (% by weight)::
Titanium alloy (TiAl6V4) according to ASTM F 136 / ISO 5832-3.
For all titanium alloy products Ti-Al6-V4: Nickel free according to ASTM F 136 / ISO 5832-3 Nitrogen 0,05% max, carbon 0,08% max, hydrogen 0,012% max, iron 0,25% max, oxygen 0,13% max, aluminum 5,5-6,5%, vanadium 3,5-4,5%, balance titanium.

Cobalt-chromium-molybdenum alloy according to ASTM F 1537 / ISO 5832-12:
Carbon 0.014% max, chromium 30.0% max, molybdenum 7.0% max, nickel 1.0% max, iron 0.75% max, silicon 1.0% max, manganese 1.0% max, nitrogen 0.25% max, balance cobalt.

The implants MONOPOLY, CONKLUSION, DIPLOMAT and COSY are anodized with oxide layers in different colors for easier identification. Color changes are caused by factors related to production and reprocessing and do not affect the functionality.

The materials are established materials for use as an implant. They are biocompatible, corrosion-resistant and non-toxic in the biological environment.

1.15 Sterility and Reprocessing

Sterile implants are supplied in double sterile packaging and are gamma sterilized in accordance with DIN EN ISO 11137. They are intended for single use only and are not reusable. Re-use can result in infection and / or loss of function, which in extreme cases can lead to the death of the patient. If not precluded on the commercial packaging or the primary packaging, a non-sterile implant may be reprocessed, provided that this is compatible with the hospital guidelines and that appropriate validated cleaning and sterilization processes have been established. Products with opened primary sterile packaging will not be accepted by SIGNUS and must be disposed of properly. Broached packaging units will not be accepted as a matter of principle.
Implants and instruments supplied non-sterile must be processed before use in accordance with hospital guidelines. The implants and instruments are shipped in implant / instrument trays provided by SIGNUS or in a suitable protective packaging for re-orders. Implants and instruments must be stored in their original packaging or in the implant / instrument tray.

1.15.1 Reprocessing

Observe the validated reprocessing procedure in the Instructions (for valid version see eifu.signus.com).

Brief instructions:

- Maximum permissible temperature during reprocessing: 137° C.
- Reprocessing approved by manufacturer
- All non-sterile products must be reprocessed in the SIGNUS sieves reprocessing
- Preparation before cleaning, ultrasonic bath if necessary
- Recommended cleaning: Machine, washer-disinfector disinfection device, validated according to EN ISO 15883, mild-alkaline cleaner.
- Recommended disinfection: Thermal, > 90° C, > 5 min. resp. A0 value ≥ 3000
- Drying: Up to 120° C, 20 min.
- Packaging: According to EN ISO 11607 and EN 868.
- Recommended sterilization: moist heat, 132° C - 137° C, 4 min. holding time, EN ISO 17665

- Sterilized goods must be dry
- Before return, the implant and instrument tray used must undergo a validated cleaning procedure. This must be documented on the accompanying certificate provided and enclosed with the return shipment.

1.16 Conformity assessment under MDR

The conformity assessment of the products to the MDR ("the product approval") was done on the base of clinical data for the devices themselves and in the case of COSY on clinical data of equivalent device (previous generation).

2 Clinical data on MONOPOLY / CONKLUSION / DIPLOMAT / COSY

2.1 Current knowledge / state of the art

Posterior screw / rod fixation is an accepted and up-to-date procedure for immobilization of spinal segments. Various textbooks describe the procedure (1) (2) (3) (4).

In case you are not familiar with the technique of pedicle screw fixation and posterior spinal immobilization in general you should not use the systems. The provided information in the instructions for use, the product information and this SSCP is not sufficient to perform spinal fixation procedures.

Spinal fixation is performed to treat instabilities (for example after tumor surgery or fractures), degenerative conditions like degenerative disc disease or deformities.

The decision-making process to select patients suitable for spinal instrumented surgery is described in various textbooks. The 2020 textbook from Bridwell et al (1) for example presents different cases and discusses the correct treatment strategy.

There is no accepted consensus concerning the best implant dimensions and material. Most pedicle screws are today made from titanium and its alloys. However, also stainless-steel implants are available. CoCr implants (specifically rods) are stiffer compared to titanium and may offer advantages in situations demanding high rigidity. Thoracolumbar rods mostly have 5.5mm or 6mm diameter. Again, there is no clear literature supporting claims on superiority of one to the other (1).

2.2 Clinical data on the device itself

2.2.1 Clinical evidence from post-market surveillance activities

Thoracolumbar systems (DIPLOMAT, CONKLUSION, MONOPOLY):
At the time of this report (until 11/2025) >800 000 components of the different systems have been distributed. Since the start of complaint records in 2012, there were 9 complaints on 12 parts that were considered justified, corresponding to very low 0.002% total justified complaint rate because of screw breakage, loosening of the tulip from the screw, or stucked tulips. One case was caused by sclerotic bone of the patient, in the other cases causes remained unclear. The total rate of complaints including unjustified complaints corresponds to a low 0.03%.

To date, there have been a total of two incidents regarding DIPLOMAT to be reported to the authorized bodies in the EU (in 2016 a user error by a surgeon led to revision surgery, and in 2021 a severe fall of a patient led to screw breakage). These are known risks taken into account in the risk analysis and/or the IFU. No recalls or other Field Safety Corrective Actions (FSCA) had to be performed since the market launch of the systems. In addition, searches for reports from third parties on SIGNUS products were carried out in the FDA database MAUDE and in the TGA database DAEN. In the DAEN database no entries were found. The MAUDE search revealed 2 entries for DIPLOMAT from 2019: One reports on a

revision surgery because of improper application of the tulip on the screw by the surgeon. The other is on a complaint regarding a set screw which had loosened from the tulip and required a revision surgery after one week. The complaint was considered not justified, as the claimed tulip and screw had no functional or structural deficits and secure attachment of the rod was possible with the product without restriction. The findings indicated a result of mishandling during the first implantation surgery.

As part of its PMCF activities, SIGNUS documents the outcomes of surgeries attended by salespeople or other personnel. As a result of the first 660 accompanied surgeries with CONKLUSION, DIPLOMAT, DIPLOMAT Deformity and MONOPOLY, the mean operation time was 3,91 hours and the mean age of the patients was 63 years. ~8% of the accompanied cases were revisions, with ~5% affecting SIGNUS` screw rod systems. Reasons for revisions were in most cases screw complications such as screw loosening or breakage, and it was also reported that a surgeon used a rod that was too long and had to be replaced. Furthermore, revisions also had to be performed due to adjacent level disease and recurrent spondylodiscitis. The doctors rated the operations with the Screw Rod System (CONCLUSION, MONOPOLY, DIPLOMAT, and DIPLOMAT Deformity) to 100.0% as good and were 98.1% satisfied with the operation itself. 97.9% of the surgeons were satisfied with the handling of the instruments.

Cervical systems (COSY): As the system has been placed on the market but has not yet been distributed to clinics for implantations, there is no specific data from post-market surveillance.

SIGNUS also monitors the field with respect to adverse event reports and recalls by market competitors on comparable products. Searches in the databases of BfArM, FDA, Swissmedic, MHRA, and TGA. An analysis of the period from 2017-2024 revealed 41 notifications (doublings excluded) that were directly transferable to the SIGNUS screw-rod system, and 44 additional notifications that were transferable to either all SIGNUS products, to all sterile goods/products, or to all implants. All detected failure modes represent known risks, and SIGNUS has established sufficient measures to prevent these failures. No new actions by SIGNUS were required. In addition, a search in the FDA TPLC database was performed for the period from 2017 to 11/2024 to gain an overview of potential adverse events on screw-rod devices. The most frequent reported events in the database were breakage, migration, and pain. The analysis confirmed the findings in the risk analysis and the SOTA.

Regarding registries, SIGNUS fully supports the concept of collecting data in registries and is also committed to participate in setting up a registry. However, so far most inquiries at several registries revealed either no data on SIGNUS implants at all, or the data sets were incomplete or contained such low case numbers that the registry data in their current form are insufficient to provide relevant information on the performance and safety of the SIGNUS screw-rod systems. One register extract from the British Spine Registry contained data for DIPLOMAT on 14 patients. The data analysis showed a very heterogeneous data collection, and for part of the patients no preoperative data collection or no follow-up were

available. Of the remaining 10 patients not all filled out the questionnaires equally and the data regarding the follow-up of the individual categories is not complete. Despite the heterogeneous data collection and the small number of patients, these data support the findings from publications (15) (16) that DIPLOMAT performs as intended.

Expert opinions were gathered for CONKLUSION and DIPLOMAT including DIPLOMAT MIS and DIPLOMAT Deformity. All confirm the indications stated in the IFU. They report very low complication or revision rates. Surgical risks are considered comparable to those of other systems, whereas two surgeons mention reduced blood loss using the SIGNUS hooks when compared to other systems. In one report, patient satisfaction is estimated to 95%. All reports confirm that the SIGNUS screw-rod systems are safe to use and able to achieve reproducibly good results in spinal stabilization.

In conclusion, SIGNUS continuously monitors the safety and performance of the implants. There were no reports questioning the safety or performance of the implants.

2.2.2 Clinical evidence from published clinical studies

2.2.2.1 CONKLUSION

Five clinical papers report results on patients treated with the CONKLUSION system. Only 2 of the papers (5) (6) only use CONKLUSION (198 cases). The other 3 papers (7) (8) (9) do not specify the number of patients treated with CONKLUSION and the number treated with alternative pedicle screw systems. Two papers mainly reported in trauma cases (5) (6), one on spinal infection (8) and two on degenerative conditions (7) (9). The papers report on implant related complications such as screw loosening or misplacement, however, none of the papers mentions and specific malfunction of the CONKLUSION. CONKLUSION is regarded as a standard pedicle screw system as mentioned in the textbook section (10).

2.2.2.2 DIPLOMAT

2.2.2.2.1 DIPLOMAT Deformity (formerly referred to as LSZ)

DIPLOMAT LSZ is a lamina hook system. Publications are mentioning the previous name LSZ3. There are 15 publications in Russian language reporting clinical results on the system. However, most of these papers report overlapping results. Data on three of these publications is reported here (11) (12) (13). Paper (13) reports results on hybrid constructs and compares this to 2 other groups. However, the results of these 2 other groups are not given. We still include these papers are they do report on performance and safety of the implants.
Paper (11) and (12) probably have overlapping patient populations. Although the total number of patients is different, the similarity in reported complications suggest that the same results are described.
Paper (14) from Mandare et al in Romania describes cases of failed back surgery treated "mostly" with the LSZ system. The exact number of cases or implants is not reported in the

paper. The paper does not comment on the performance of the implants, however, 92.85% (13/14) of the patients were satisfied indicating correct function of the implant.

Data on the LSZ3 is available for idiopathic scoliosis with hook only constructs or hybrid constructs (11) (12) (13).

2.2.2.2.2 DIPLOMAT pedicle screws

Two papers report on the DIPLOMAT pedicle screw system: The paper of Banat et al (15) specifically assessed the frequency and reason for early revision surgery. Overall, 13 patients (8.5%) had revision surgery within 4 months. The data was collected from all patients operated by the clinic (mainly degenerative, but also tumors, infection and trauma). Percentage of revision with highest in the degenerative patients (7/52, 13.5%) and lowest in trauma patients (1/39, 2.5%).
The authors discuss the reasons for failure and identify obesity as one main factor. Within the discussion they state that the pain reduction measured after surgery is higher compared to the literature value. However, their revision rate might also be higher. They give early postoperative mobilization as one possible explanation. The authors report that no rod breakage was seen, radiolucent areas around screws were found in 20% of patients after 3 months and 31% after 12 months.
The authors do not specifically discuss the possible influence of the used pedicle screw system on the revision rate.
It seems unlikely that the DIPLOMAT System should be associated with higher radiolucency around the screws compared to other systems. The material of the system (TAV) is standard in spine surgery. Overall, the paper confirms that the DIPLOMAT System is safe and performing as intended.

The other paper by Novak et al (16) describes a specific technique for pedicle screw insertion. The study reports results on fixation in the lumbosacral region. Indications for surgery were mostly degenerative scoliosis and revision of previous spine surgery. The complication rates (8.3% non-fusion, 1.2% screw fracture) are therefore difficult to compare with standard primary surgery. The authors do not specifically comment on safety or performance of the implant system used.

2.2.2.3 MONOPOLY

One paper from Buric et al (7) describes 15 patients treated with MONOPOLY (it is not 100% clear what the total patient number in the paper is). All patients fused and no device related complications were reported. In a paper from Biscevic et al (17) the use of the system is documented, however, no performance data is reported and the number of implants not specified. The paper does not report on issues with the pedicle screws used.

2.2.3 Unpublished studies

2.2.3.1 COSY

One expert report / unpublished study provides information on clinical performance and safety of the COSY. The COSY system was originally marketed under the name "Gibralt", there are minor technical differences between the products.
Main indication was stenosis in conjunction with other morbidities such as myelopathy or radiculopathy. Implants were used between C2 and T3. There were in total 26 patients. According to Odoms criteria 95.7% of the surgeries were rated as good or excellent, in one patient (4.3%) the success was rated as "Fair".
There were 2 cases of screw loosening: One patient was followed up for 19 months and did not develop any adverse events due to the potential loosening. The other patient also did not develop symptoms and both patients improved after the surgery. No revisions for hardware reasons were necessary. The authors conclude that the system functioned as intended.

2.2.4 Summary of clinical study data

There are several publications in which the use of the systems is documented (see 2.2.2). These papers do not aim at comparing different screw / rod systems with the aim of finding advantages / disadvantages of one to the other. The papers see screw / rod systems as standard tools and expect standard performance. None of the papers suggests any elevated complication or adverse event rates from the use of the system. In our view, the papers confirm that the systems work as intended.

The revision rate of 8.5% for DIPLOMAT reported in one paper (15) is higher than the threshold value defined for the clinical evaluation (5%). We consider this acceptable for several contextual factors from the study and related research:

1. Variability in literature rates: Reported revision rates for material failure in screw-rod spinal systems range widely from 1-12% across studies, with some as high as 37-63% in specific subgroups (e.g., complex adult deformities or tumor cases). 8.5% falls squarely in the middle of this spectrum, suggesting it's not an outlier but reflective of real-world outcomes in heterogeneous patient populations.
2. Study-specific factors: failure risks due to poorer bone quality, higher mechanical stress, or delayed healing. There may be selection bias toward more severe or comorbid patients, potentially inflating rates compared to simpler degenerative cases in community settings where <5% might be more achievable.
3. Early detection and timing: Unlike many studies relying on X-rays or later follow-ups, this one used routine CT scans at 3 and 12 months, which allowed for earlier identification of subtle issues like radiolucent zones (seen in 20-31% of patients overall). This proactive imaging likely captured failures sooner, contributing to the observed rate – other studies with less sensitive monitoring might underreport early issues, making their rates appear lower (e.g., closer to 2-4%). The authors note that revisions were only pursued when radiological findings correlated with clinical symptoms (e.g., instability and pain), not

based on imaging alone, which helps explain why not all potential issues (like transient radiolucent zones) led to surgery.

4. Protective measures and comparisons: The study employed standardized surgical techniques (e.g., open pedicle screw placement, bone grafting, and PEEK cages where appropriate) and multimodal postoperative care (analgesia and early physiotherapy), which actually led to better pain outcomes than some benchmarks. Infections were rare (only 1 case), ruling out a major confounder. In contrast to a strict <5% threshold, which might apply more to low-risk elective fusions, the 8.5% here is reasonable for a mixed-pathology group and aligns with or better rates in similar high-complexity studies (e.g., 6.7% rod breakage in primaries or 21% overall revisions in percutaneous fixations).

Overall, while 8.5% exceeds the <5% ideal, it's justifiable as a realistic figure for this setting, emphasizing the need for tailored risk assessment rather than a one-size-fits-all benchmark. If aiming to reduce rates below 5% in practice, it should be focused on patient selection (e.g., optimizing BMI), enhanced fusion techniques, or alternative materials could help, as suggested in related research.

For CONKLUSION one paper (5) reports higher revision rates compared to the performance benchmarks. We however anyhow rate the clinical data as probably positive since (i) the paper does not indicate that these issues are related to the system and (ii) other data points indicate performance within the expected values.

Concerning DIPLOMAT, another issue in one paper was the rate of radiolucent zones around implants which was higher compared to the SOTA. However, the authors of this paper clearly indicated that they regard the system as safe and don't see indications that these performance differences are system related.

2.3 Overall clinical data summary

The post-market surveillance together with the clinical data shows that the SIGNUS posterior screw / rod systems function as intended. The overall data continue to support the safety and effectiveness of the Screw Rod Family, when used as intended. Based on the current state of the art, data from the field concerning product performance, and critical literature analysis related to the product, the medical benefits of the Screw-Rod-Family are concluded to outweigh the risks associated with the device. It is concluded that the potential side-effects, when considering the intended performance, produce positive overall user benefits when compared to risks.

2.4 Planned further clinical data gathering (Post market clinical follow-up, PMCF)

The current PMCF plan lists the following activities:

- SIGNUS analyzes data from publicly available sources (vigilance and literature databases) in order to identify additional clinical data on the systems.
- SIGNUS accompanies surgeries and monitors the results. The reports about these surgeries are analyzed to identify any derivations from the anticipated performance and safety variables.

- For DIPLOMAT, SIGNUS is running a study (in combination with the lumbar vertebral body replacement device POSEIDON ST) to gather more information on the clinical performance of both systems.
- As there is only limited data on COSY, SIGNUS is currently planning a prospective study with proposed start in 2026 to gather additional data.

2.5 Expected performance and complication rate

Based on literature on similar devices and on the literature on the screw / rod systems themselves, the following performance can be expected, and number of complications / adverse events must be expected. The rates may vary greatly depending on the patient group treated.

Table 8: Expected performance and complication rate

Performance and safety	Value in %
Fusion rate (performance)	≥91.9%
Implant breakage (safety)	≤6.13%
Implant loosening (safety)	≤12%
Revision rate (safety)	≤5%

Adjacent segment disease

Adjacent segment disease is partly a result of the fusion procedure itself (increase mobility at the adjacent segment). However, it could also be influenced by the hardware which interacts with the adjacent level. The cervical spine is anatomically smaller compared to the thoracolumbar spine. As such, hardware interaction with the adjacent level is more likely.

The rate of adjacent segment disease leading to surgery is expected to be lower than 10%.

Specific (performance) benchmark deformity surgery (including hooks)

Reduction of cobb angle

A deformity treatment device (hooks or pedicle screws) is expected to be able to reduce the curve on average by 50% in idiopathic scoliosis surgery.

Specific (performance) benchmark degenerative surgery

Pain reduction

Neck, arm or back pain are typical indications for degenerative spine surgery. Pain should be reduced in at last a Minimum Clinically Important Difference (MCID) for improvement in preoperative pain scores at final follow-up (18). Using the Minimum Clinically Important Difference (MCID) avoids difficulties with different reporting methods in individual papers.

A VAS reduction of greater than 2.5 on 10-point scale is regarded as MCID (18).

Specific (performance) benchmark trauma surgery

There is not reasonably expected complication or performance rate for trauma surgery as this depends on the procedure itself. Pedicle screw systems should be stable enough to fixate the spine until bony fusion is achieved.

Procedure related complications:

The review by Wang (19) analyzes complications of pedicle screw placement in comparison to cortical bone trajectory placement.

The total complication rate for pedicle screws is 86 of 376 patients (average 22.8%; between 3.3% and 21.1% in the included studies).

Intraoperative complications occurred in 41 of 339 patients (average 12%; between 2.5% and 23.9% in the included studies).

Postoperative complications occurred in 45 of 376 patients (average 12.2%; between 3.1% and 35.9% in the included studies).

The subject devices are expected to perform similar to other posterior screws systems and thus similar complication rates can be expected.

3 Reference to any common specification(s), harmonized standard(s) or guidance document(s) applied

Common specification(s) applied:

During the preparation of the report, the homepage of the EU Commission was searched for applicable Common Specifications. No applicable Common Specifications could be found which had to be taken into account in the preparation of this report.

Harmonised standards applied:

SIGNUS implants and instruments comply with the requirements of the MDR.
The standards committees aim to have completed the harmonization of the applicable standards to the MDR by 2024.
Compliance to harmonized standards or if applicable the state of art is demonstrated in the conformity assessment process, documented in the General safety and performance requirements evaluation by annex I of regulation 2017/745 MDR. Therefore, a summary of the product-specific standards used is provided. For further information on the normative background, please contact SIGNUS directly.

The biological evaluation is based on the standards DIN EN ISO 10993-1:2021-05.

The requirements of the standard DIN EN ISO 14971:2022-04 for the application of risk management are met.

Generally, the systems have been designed and tested according to more than 60 national and international standards. Readers interested in this list should contact SIGNUS for a copy. The respective standards must be purchased, as SIGNUS is not allowed to provide copies due to intellectual property rights.

The following guidance documents were used for the SSCP and the clinical evaluation of the products:
MEDDEV 2.7/1 Rev. 4 (2016)
MDCG 2019-3
MDCG 2019-9
MDCG 2020-5
MDCG 2020-6
MDCG 2020-7
MDCG 2020-8
MDCG 2020-13

4 Clinical benefit / risk benefit evaluation

The devices are indicated for use for treatment of degenerative conditions, deformities and situations leading to instability (trauma, tumours etc.). Clinical benefits of such procedures are the reduction of pain and disability, restoration of the spinal stability and curve or cosmetic factors (in the case of deformities).
Instability treatment, for example for fractures, mainly has the goal in restoring the anatomy and preventing secondary damage pain (1).

Indication	Benefit	Risk	Discussion / Evaluation
Treatment of degenerative conditions	The benefit of fusion procedures is mainly the reduction of pain and thus the restoration of function and mobility. These are mostly elective surgeries.	Spine surgeries bear the risk of serious adverse events including permanent disability or death.	As degenerative procedures mostly could also not be treated, it is mandatory that the surgeon discusses the risks and benefits with the patient. Generally, fusion procedures are accepted treatments for degenerative diseases and the risk / benefit profile is positive. However, as the surgeries are mainly elective, the risk / benefit is patient specific and must be assessed individually.
Traumatic injuries and tumors; general instabilities of the spine.	Restoration of the spinal anatomy or stabilization of the spine in order to prevent subsequent injury and to allow healing.	Spine surgeries bear the risk of serious adverse events including permanent disability or death.	In severe instabilities due to fractures / tumors there are little alternatives to instrumented stabilization (discussed below). As such the risk / benefit profile in severe cases is not controversial. What types of instability require instrumented stabilization is, on the other hand, highly controversial. Society guidelines such as the AO surgery reference provide insight on which patients profit from surgery (20).
Deformities	Reduction of the deformity prevents progression of the disease including problems with stature / spinal balance and cosmesis. Long term disability is prevented.	Spine surgeries bear the risk of serious adverse events including permanent disability or death.	A positive risk / benefit profile on severe scoliosis / kyphosis cases is not controversial. Whether a deformity requires instrumented surgery needs to be assessed on an individual patient level on the basis of society guidelines and training.

5 Alternatives to the use of SIGNUS Screw / Rod systems

5.1 Alternative implants

There are various screw / rod systems from many suppliers on the market which function in a similar way with similar performance compared to the SIGNUS systems. Alternatives to pedicle screws are other stabilization devices such as anterior or lateral plate / screw systems, trans-facet screws etc.

Indication	Benefit	Risk	Discussion / Evaluation
Treatment of degenerative conditions	There are no high-quality reports proving superiority or inferiority of different fusion systems.	There are no high-quality reports proving superior or inferior risk profiles of different fusion systems.	In specific surgical situations different systems might provide different benefits or risks. Example: Anterior surgery only might in some cases be superior to posterior only fixation or 360° (posterior or anterior) fixation. Posterior screws are a generally accepted tool. Whether there might be more suitable tools in specific situations should be carefully assessed before each surgery.
Traumatic injuries and tumors; general instabilities of the spine.	There are no high-quality reports proving superiority or inferiority of different fusion systems.	There are no high-quality reports proving superior or inferior risk profiles of different fusion systems.	In specific surgical situations different systems might provide different benefits or risks. Example: Anterior surgery only might in some cases be superior to posterior only fixation or 360° (posterior or anterior) fixation. Posterior screws are a generally accepted tool. Whether there might be more suitable tools in specific situations should be carefully assessed before each surgery.
Deformities	There are no high-quality reports proving superiority or inferiority of different fusion systems.	There are no high-quality reports proving superior or inferior risk profiles of different fusion systems.	In specific surgical situations different systems might provide different benefits or risks. Example: Anterior surgery only might in some cases be superior to posterior only fixation or 360° (posterior or anterior) fixation. Posterior screws are a generally accepted tool. Whether there might be more suitable tools in specific situations should be carefully assessed before each surgery.

5.2 Alternative surgical treatments

Alternatives to instrumented fusion may be posterior decompression without implants, anterior or lateral fixation with implants or posterior surgery with alternative implants (for example interspinous process fixation).
As a general rule, the least invasive procedure sufficient to solve the underlying issue should be preferred. A discussion of all surgical alternatives goes beyond the scope of this report. We strongly suggest to consult state-of-the-art textbooks (for example Bridwell et al (1)) and society guidelines (for example the AWMF guidelines at www.awmf.org) for details.

Indication	Benefit	Risk	Discussion / Evaluation
Surgical treatment of degenerative conditions without implants	Similar benefits as with instrumentation (reduction of pain and disability)	Possibly less risks as the placement of implants is invasive by itself. Pedicle screws for example can penetrate the spinal canal or other structures causing injury.	Generally, the least invasive procedure should be the first consideration. Implants cause additional risks but also additional stabilization and might prevent secondary surgery due to recurrence of the condition. The decision on whether to stabilize with implants should be taken on an individual patient level.
Surgical treatment of Traumatic injuries and tumors; general instabilities of the spine without implants.	Similar benefits as with instrumentation (stabilization of the spine)	Possibly less risks as the placement of implants is invasive by itself. Pedicle screws for example can penetrate the spinal canal or other structures causing injury.	Generally, the least invasive procedure should be the first consideration. Implants cause additional risks but also additional stabilization and might prevent secondary surgery due to recurrence of the condition. The decision on whether to stabilize with implants should be taken on an individual patient level.
Surgical treatment of Deformities without implants	Similar benefits as with instrumentation (reduction of deformity)	Possibly less risks as the placement of implants is invasive by itself. Pedicle screws for example can penetrate the spinal canal or other structures causing injury.	Generally, the least invasive procedure should be the first consideration. Implants cause additional risks but also additional stabilization and might prevent secondary surgery due to recurrence of the condition. The decision on whether to stabilize with implants should be taken on an individual patient level.

5.3 Non-surgical treatment

Patients can (and should) be treated with physiotherapy and pain medication before considering surgery. Surgery should only be considered if (i) conservative therapy failed or (ii) the severity makes the use of conservative therapy not promising.

Indication	Benefit	Risk	Discussion / Evaluation
Non-surgical treatment of degenerative conditions	Similar benefits as with instrumentation (reduction of pain and disability)	Less risks as with surgery.	Pain due to degenerative conditions may spontaneously resolve. Any degenerative condition should primarily be treatment with non-invasive methods. Surgery should only be considered if non-surgical methods fail.
Non-surgical treatment Traumatic injuries and tumors; general instabilities	Similar benefits as with instrumentation (stabilization of the spine)	Less risks as with surgery.	If non-surgical methods are not promising for stabilization of the spine, surgery might immediately be indicated. Non-surgical methods are less risky but to little stabilization of the spine causes risks itself. Whether nonsurgical stabilization is sufficient must be assessed on a single patient level.
Non-surgical treatment Deformities	Similar benefits as with instrumentation (reduction of deformity)	Less risks as with surgery.	Curve reduction with braces etc. should always be the first line of treatment. Surgical correction should only be considered if non-surgical options fail.

6 Suggested training for users

The use of the implant itself is not challenging for experienced spine surgeons. Before performing surgery, the user should carefully read the product information and test all instruments.

SIGNUS suggests undergoing a training course for the Screw / rod systems. Such courses are offered by SIGNUS and individually tailored to meet the need of the user. If users are insecure on any aspect of instruments or implants a SIGNUS representative should be consulted. There are no mandatory trainings for the device.

Spinal surgeries should strictly be limited to experienced spine surgeons with multiple years of training in the respective surgical area.

Part 2: Lay people

This section of the document shall provide information to lay people, specifically patients. The information is structured similarly to the information for medical professionals (see above) and contains qualitatively similar information in less detail and in a less medical language.

If more details are required there are the following options:

→ Consult the part for professional users
→ Contact SIGNUS and ask for the specific information
→ Discuss the question with your health care professional

7 Device description

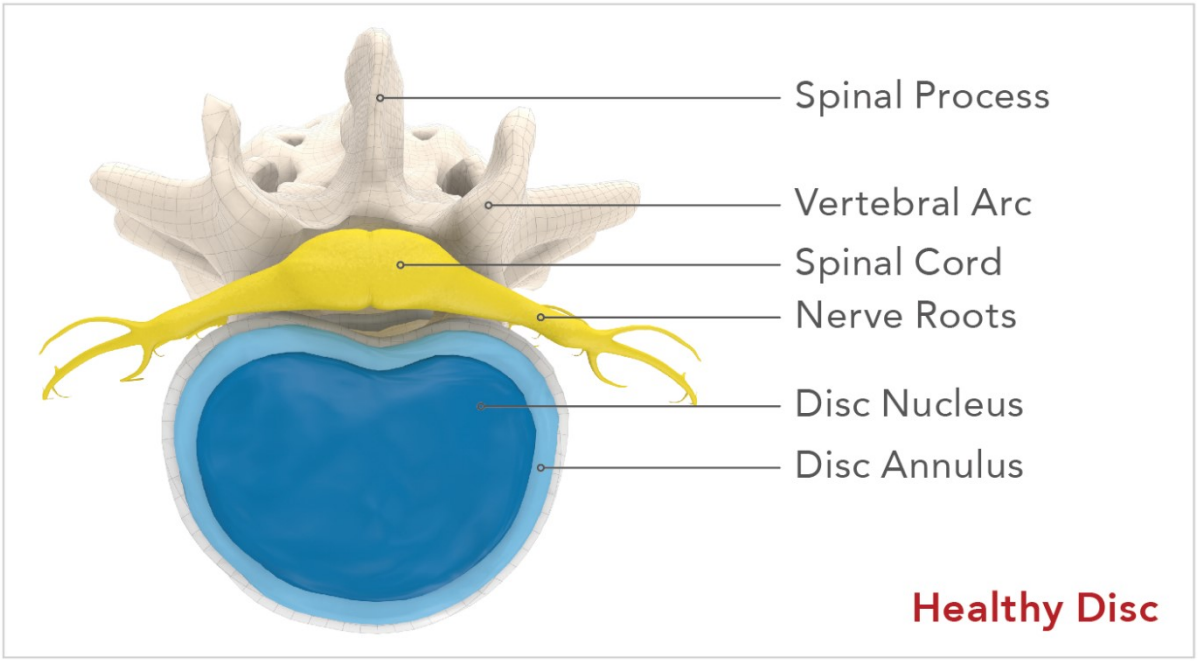
The spinal column, also known as the columna vertebralis or colloquially as the backbone, is the central load-bearing element in the skeletal system. It supports the body and enables an upright posture. It represents our center of rotation, making motion sequences to different directions possible. The Spine is not just the boney core, it also connects all other parts of the skeleton together. In addition, the vertebral or spinal canal encloses and protects the sensitive spinal cord that lies within it. Changes to the complex spine system may lead to impaired motion and causes severe pain. Surgical procedures on the spine are among the most frequently performed operations. A surgical procedure is often associated with pain, anxiety and limitations in your daily movements.

With our patient information we would like to tell you about different treatments for persistent symptoms in the spine.

Important information: Please keep in mind that SIGNUS Medizintechnik GmbH just provides general information about the treatment. Specific questions can only be answered by your doctor.

The Spine

The spine is an extraordinarily complex system of bones, cartilage, muscles, ligaments and nerves that combines both static and dynamic functions. It also protects the spinal cord that lies within it. The spine is divided into the cervical (Cervical, C1 – C7), thoracic (Thoracic, TH1 – TH12) and lumbar (Lumbar L1 – L5) regions. Adjacent to the lumbar is the sacrum. The sacrum is an ossification of four to five vertebrae fused together to form a unified bone. Between the individual vertebrae sit the intervertebral discs. Together with the ilium, the coccyx forms the sacroiliac joint (SIG). This provides the connection of the spine to the pelvis. If you look at the spine from the side, you can see a double-S-shaped curvature, which serves to protect against shocks and to best cope with the stresses and demands of everyday life. This curvature is created by the different bending of each spinal segment. The cervical and lumbar spine is curve forward, which is called lordosis. The thoracic spine and sacrum, on the other hand, curve backward and are termed kyphosis.



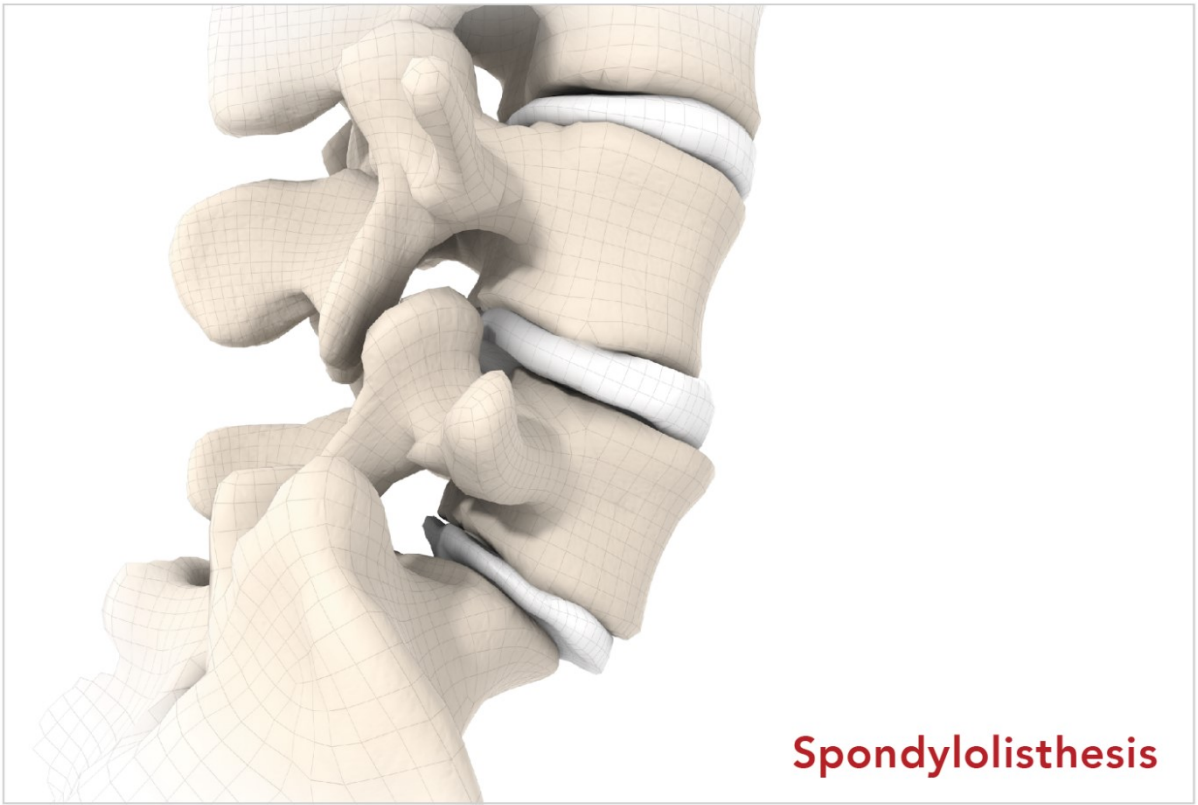


Figure 9: A vertebral body with disc (above); a slipped vertebral body (Spondylolisthesis) below.

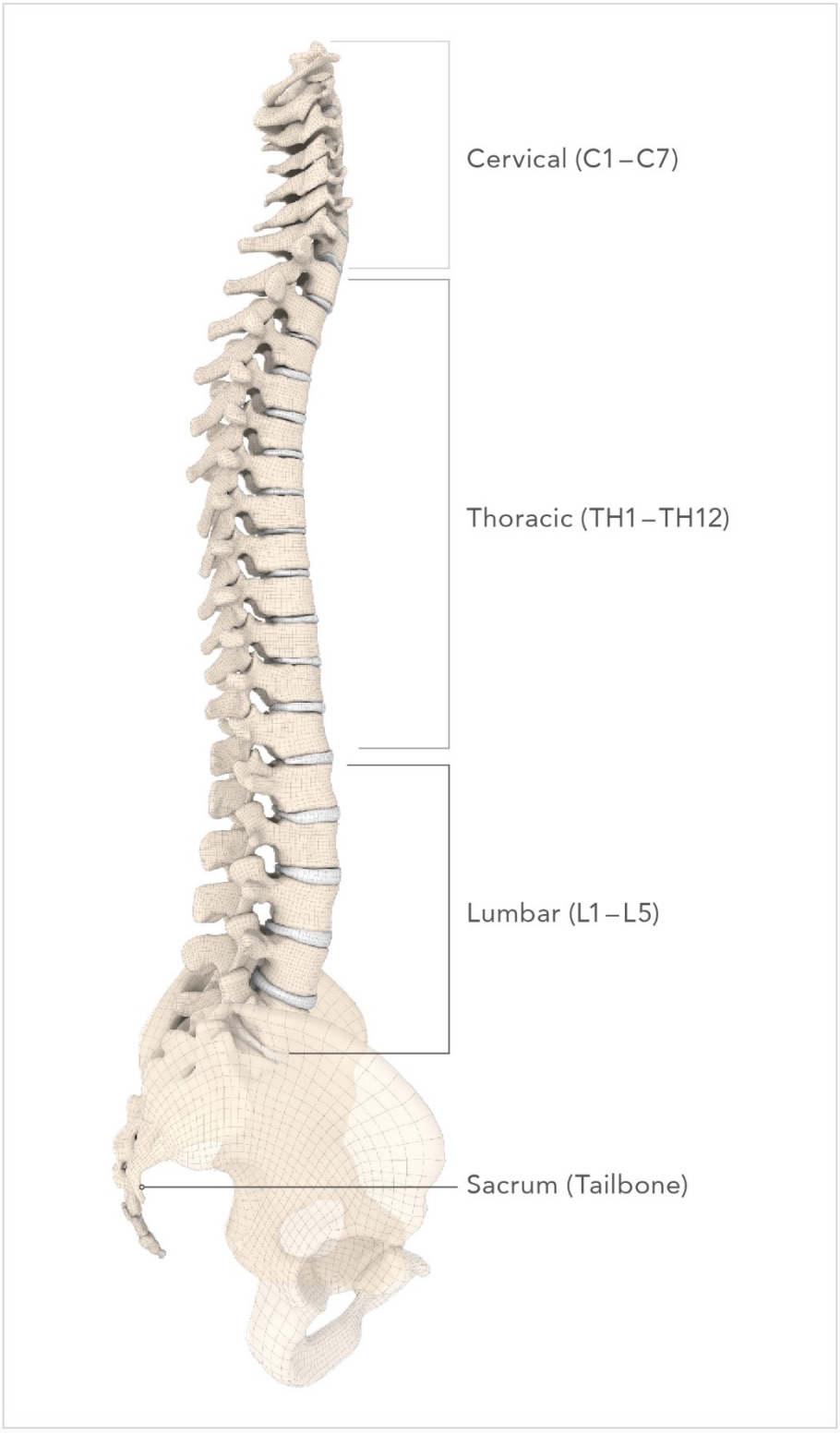


Figure 10: Anatomy of the spine

7.1 Thoracolumbar system

If symptoms cannot be eliminated or sufficiently alleviated by conservative therapy or appropriate pain medication, surgery may be necessary. Depending on your personal clinical picture, this may require a rod-screw system, whereby the diseased part of the spine is stiffened (fused). This could be for example, in the case of massive constriction of the nerves or spinal cord (spinal canal stenosis), in order to prevent permanent damage, or in the case of instabilities such as spondylolisthesis. The goal is always to ensure a long-term improvement in your symptoms. In the case of a treatment using a rod-screw system, an additional insertion of a cage (shaped placeholder) is often required.

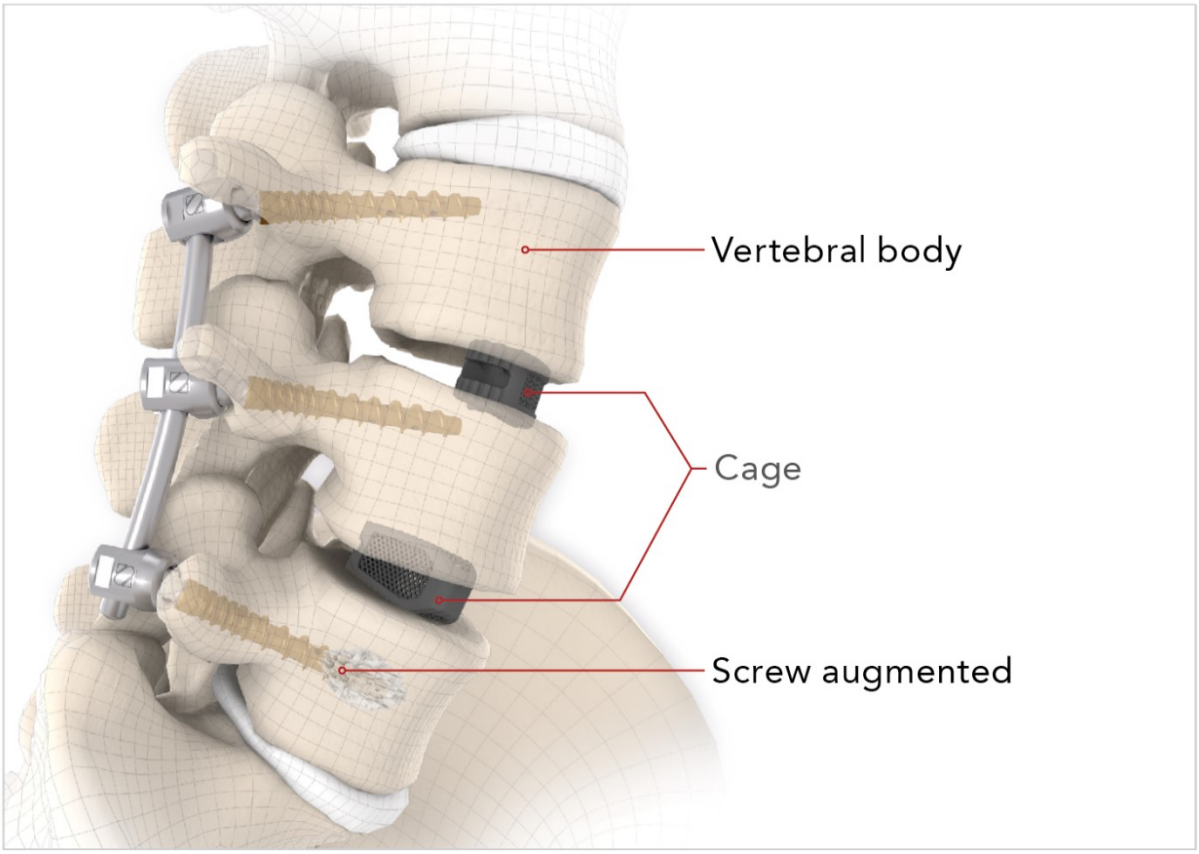


Figure 11: A fixation with pedicle screws.

Posterior Pedicle screw systems (DIPLOMAT/ MONOPOLY / CONKLUSION)

The operation is usually performed in the prone position on special positioning pillows. Through a skin incision on the back, the muscles are pushed aside and the spine is exposed. Pedicle screws are then inserted into the vertebral bodies and attached with connecting rods. Often it is as well necessary to remove excess bone tissue or disc material, which presses on the sensitive nerves and thus causes the pain. Together with the screws, after removal of the intervertebral disc, a shaped placeholder (cage) is usually also inserted into the intervertebral space. It restores the physiological (natural) height of the disc segment.

The screws and rods ensure the stability of the spine and guarantee immobilization until the bone, with or without the cage, has fused (stiffened) the vertebral bodies .

Identification of the Implant

Information identifying your implant, as well as the SIGNUS name, address and website can be found on your implantation card, which will be given to you by your treating physician.

DIPLOMAT/ MONOPOLY / CONKLUSION Material

The implants are made of the following materials:

- Titanium alloy (Ti-6Al-4V) according to ASTM F 136 / ISO 5832-3
- Cobalt-chromium-molybdenum alloy according to ASTM F 1537 / ISO 5832-12

These materials are established for implant use. They are biocompatible, corrosion resistant and non-toxic in the biological environment. For easy identification, the implants are coated with oxide layers of different colours. Colour changes are due to production and processing and do not affect functionality. The safety and compatibility of SIGNUS spine screws in an MRI environment has not been determined. The products have not been tested for heating, migration or artefact formation in an MRI environment.

Figure 12: A pedicle screw (MONOPOLY). Cement can be injected into the screw and exits from the holes in the lower part of the screw.

7.2 Cervical system (COSY)

Cervical posterior fixation generally works similar to lumbar fixation. Screws are inserted into the bone and connected by rods.
Due to the smaller anatomy the screws and rods are also smaller. As the anatomy of the cervical vertebral bodies is variable, there are different projections in which screws can be inserted (see Figure 13: Screw trajectories in the cervical spine).

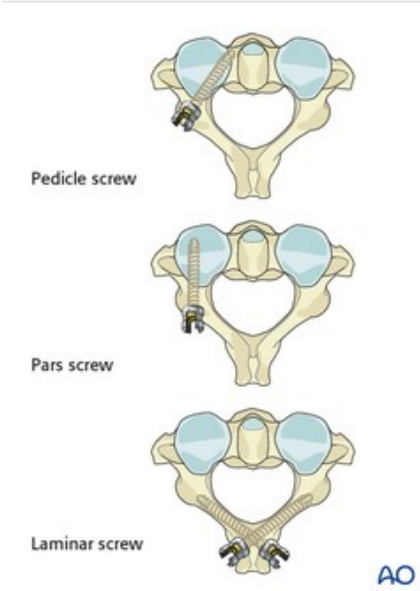


Figure 13: Screw trajectories in the cervical spine (20)

The COSY Spinal System

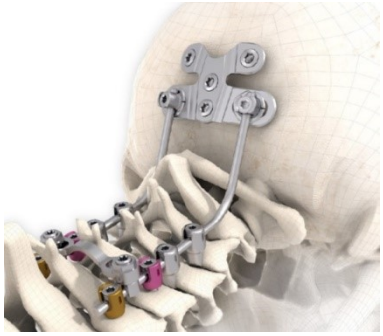


Figure 14: COSY Construct

The system consists of screws which are connected by rods. Additionally, the rods can be connected to the scull bone (occiput), as shown in Figure 14 above.
The components of the COSY spinal system are made of a titanium alloy. Rods are available in titanium alloy and cobalt-chrome alloy versions. The exact material specification is identical to the thoracolumbar systems as described in 7.1. This system can be used independently or in conjunction with SIGNUS screw rod System (e.g.: DIPLOMAT, DIPLOMAT Deformity and MONOPOLY).

7.3 Generalities

Table 9: Administrative particulars (Section A-MDCG 2020-13)

Aspect	Description
Risk Class according to Regulation (EU) 2017/745 (MDR):	Implants: Class IIb, Class III* Classification in accordance with MDR Annex VIII, rule 8,indent 9 *Classification in accordance to MDCG Guidance 2021-24 (valid for hooks that fix the rod on the spinal column)
Manufacturer(s) name and SRN:	SIGNUS Medizintechnik GmbH Industriestr. 2 63755 Alzenau DE-MF-000006200
Notified body:	mdc medical device certification GmbH
Notified body number:	0483
E-mail contact of NB:	mdc@mdc-ce.de
Telephone contact of NB:	+49 711 253597-0
Active Medical Device	no
Basic UDI-DI	DIPLOMAT: 040784401050081041146 DIPLOMAT steril: 040784401050081042149 DIPLOMAT CoCr: 04078440105008204114H DIPLOMAT CoCr steril: 04078440105008204214L DIPLOMAT Deformity*: 04078440105008105114B DIPLOMAT Deformity steril*: 04078440105008105214E CONKLUSION: 04078440105005104112X CONKLUSION steril: 040784401050051042132 CONKLUSION Haken*: 040784401050051051134 CONKLUSION Haken steril*: 040784401050051052137 MONOPOLY: 040784401050141041133 COSY: 04078440105029104115M COSY steril: 04078440105029104215Q COSY CoCr: 04078440105029204115Y COSY CoCr steril: 040784401050292042163 COSY Haken*: 04078440105029105115S COSY Haken steril*: 04078440105029105215V
Year of first CE certification	CONKLUSION: 2003 MONOPOLY: 2007 DIPLOMAT Deformity – LSZ: 2011 DIPLOMAT: 2014 COSY: 2021

7.4 Intended Purpose

7.4.1 DIPLOMAT / DIPLOMAT Deformity / CONKLUSION / MONOPOLY

These systems are intended for stabilization of the thoracolumbar spine. The aim is to fuse together the spinal bone segments (vertebral bodies) in order to stop motion (see chapter 7.1). This might be necessary for example due to degenerative changes, fractures or deformities of the spine.

7.4.2 COSY

The COSY system is intended to stabilize the cervical spine (spine of the neck). The aim is to fuse together the spinal bone segments (vertebral bodies) in order to stop motion (see chapter 7.2). This might be necessary for example due to degenerative changes, fractures or deformities of the spine.

7.5 Indications for Use

MONOPOLY, CONKLUSION and DIPLOMAT are used to stabilize / fuse certain parts of the spine. Depending on the system, this includes the thoracic spine (upper and mid-back), the lumbar spine (lower back), and the sacral area (the bone at the base of the spine). They may be used for different spine conditions, such as:

- Wear-and-tear of the discs, including slipped discs (disc prolapse) or age-related degeneration, and the degeneration of the spine (spondylosis)
- Vertebrae that have slipped out of place (spondylolisthesis)
- Spinal injuries, such as fractures or dislocations
- Narrowing of the spinal canal, which can press on nerves
- Spinal deformities, such as scoliosis where the spine curves to the side instead of being straight, or an excessive rounding or arching of the back (hyperkyphosis, hyperlordosis)
- Tumors affecting the spine
- Previous spinal fusions that did not heal properly (pseudarthrosis) or earlier surgeries that were not successful

If the bones are weaker than normal – for example due to osteoporosis – the surgeon may decide to strengthen the screws with bone cement to improve stability.

The COSY Cervicothoracic - Occipital Rod-Screw System is used to stabilize and support parts of the spine in the upper neck and upper back. It helps keep these areas still so they can heal, usually as part of a spinal fusion surgery. It can be used for problems affecting the junction between the skull and spine, the cervical spine (C1–C7), and the upper thoracic spine (TH1–TH3),
This system may be used for patients with:

- Spinal injuries such as fractures or dislocations
- Instability or deformities of the spine

- Previous fusion surgeries that did not heal properly
- Tumors affecting the cervical spine
- Degenerative conditions that cause ongoing nerve irritation or spinal cord problems (radiculopathy, myelopathy)
- Neck or arm pain of caused by the damaged spinal discs, confirmed through imaging
- Wear-and-tear of the small joints of the spine that leads to instability
- Narrowing of the spinal canal (spinal stenosis)
-

The COSY system can also be used to provide temporary stability in patients with advanced cervical spine tumors when life expectancy is limited and a full fusion is therefore no longer possible.
If additional stability is needed, the COSY system can be connected to the DIPLOMAT, DIPLOMAT Deformity, or MONOPOLY systems using special connectors or "hybrid" rods.

7.6 Intended patient population

COSY, MONOPOLY, CONKLUSION, DIPLOMAT and DIPLOMAT Deformity systems are designed for use in patients whose skeleton is fully developed.
Some parts of the DIPLOMAT and DIPLOMAT-Deformity systems – specifically certain screws and hooks – can also be safely used in children and teenagers of any age.

7.7 Intended users

The implants may only be inserted by a surgeon experienced in spine surgery.

7.8 Contraindications

Spinal instrumented surgery should generally not be performed if the bone is not stable enough to allow anchorage of the implants or if there are allergies against the material.

7.9 Warnings / Precautions

You should strictly follow the instructions by the physician in terms of physical behavior and other measures after surgery. Implants can fail or break if the instructions are not followed.

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

7.10 Risks associated with the use

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Spine surgery is associated with significant risks. The likelihood of complications highly depends on the indication treated and should be discussed with your surgeon.

SIGNUS aims to control and reduce risks be different measures including the following:

- Testing of implants and instruments
- Informing surgeons on specific risks
- Post-Market Surveilance activities

Risks are also reduced by training of surgeons and by patients following the instruction of the surgeon.

The general risks associated with surgery such as injuries of vessels, organs, tissues and nerves are not listed here and should be discussed directly with your surgeon.

The following list gives a non-complete overview on possible remaining risks.

- The bones may not fuse as expected
- Sensitivity or allergic reactions to the implant materials
- Wear, bending or fracture of implant components
- Screw loosening
- Pain or recurrent pain

7.11 Clinical Benefit

The benefit of spine surgery depends on the disease which is treated:

In case of degenerative changes (changes that happen due to aging) the goal of the surgery is mostly to reduce symptoms such as pain or disability (which is often connected). The benefit of the treatment is the reduction of pain or disability.

In case of spinal fractures or spinal instabilities due to other reasons (for example tumors) the goal of the surgery is to restore the stabilization function of the spine and prevent deformation of the body which subsequently may lead to other issues such as pain, disability or paralysis. In such cases the clinical benefit is the stabilization of the spine and the prevention of further disease progression.

Deformities of the spine may lead to pain and disability. Additionally, the entire body is deformed causing unnatural appearance.

The clinical benefit of the treatment is the correction of the deformity and restoration of the correct statue.

7.12 How the devices were certified under the MDR

The conformity assessment of the products to the MDR ("the product approval") was done on the base of clinical data for the devices themselves and in the case of COSY on clinical data of equivalent device (previous generation).

8 Clinical data on SIGNUS Screw / Rod systems

8.1 Current knowledge / state of the art

The inhibition of movement between spinal segments by screw / rod systems is a standard procedure in spinal surgery.

The general principle of inserting screws in the spinal bone and connecting this with rods was developed decades ago and has not changed since then. It is considered the "workhorse" of spinal surgery.

Today, the screw / rod systems of established spinal implant companies are comparable to each other. Clinical research does not suggest that any system is superior to the other. One might compare the situation with cars: BMW and Audi both build very good cars, and the cars are not identical. However, there is no real difference in their basic performance (bringing people safely from one place to another). People might prefer one car to another because of certain comfort features which are not influencing the general performance.

Screw / rod systems, such as any implants, sometimes fail due to mechanical breakdown. It is very well possible that different fixation systems might have different failure rates (such as different cars have different failure rates). The goal of the analysis of clinical data is therefore mainly the analysis of failures of the systems.

8.2 Clinical data on the device itself

8.2.1 Clinical evidence from post-market surveillance activities

SIGNUS collects and analysis complaint data on the devices. Over all years there were 9 complaints that had to be considered justified or as unclear and that were e.g. caused in one case due to the physiology of the patient, in most other cases the underlying causes remained unclear. This is a very low rate compared to the total amount of ~800 000 components of the screw / rod systems that were marketed so far. Searches for reported issues with SIGNUS products in public databases also revealed only one case with unclear cause, and another case of mishandling by the surgeon.
So far, two events involving the DIPLOMAT system have had to be reported as so-called field safety notices (FSN) to the authorities in the EU: In 2016, a mistake during surgery required additional surgery, and in 2021, a patient suffered a serious fall, which caused one of the screws to break. Both are known possible risks already considered in the according risk management file and the product's instructions for use. No recalls or other field safety corrective actions (FSCA) were required.
Surgeries accompanied by SIGNUS personnel were rated very positively by the surgeons. All surgeons rated the systems as good, 98.1% were satisfied with the surgery itself, and nearly 98% were satisfied with how the instruments handled during the procedure.
Analysis of adverse event reports and recalls by other companies on similar products did not result in any new risks that were not already taken into account sufficiently. Furthermore, several statements by surgical experts confirm safety and performance of the implants.

8.2.2 Clinical evidence from published clinical studies and expert opinions

8.2.2.1 Published literature

Several clinical papers report on the use of the SIGNUS Screw / Rod systems. The individual study reports are listed in the section for expert users (see 2.2.2). The publications do not report any unusual failure rates for the systems.
The COSY system has been placed on the market, but has not yet been distributed to clinics for implantations. A system with similar design was used in the US (GIBRALT). For this system there is one report of a surgeon on the results with the use which also indicates that the system works without problems.

8.3 Overall clinical data summary

Data from post market surveillance and clinical data show that the SIGNUS screw / rod systems function as intended. There are no indications of any elevated failure or adverse event rates.

8.4 Risk benefit assessment

The use of the implants (the surgery) is associated with significant risks and only justified if the benefits of the treatment are higher compared to the risks.
In general, posterior spine screws are well established implants with known risks. On average the risks of the surgery are lower compared to the benefits.
This might be different on an individual level: If surgery is performed to reduce pain you should carefully consult with your physician if you are willing to accept the risks. If the pain still allows a satisfactory life, you might consider to live with the pain and not accept the risks.

8.5 Planned further clinical data gathering (Post market clinical follow-up, PMCF)

SIGNUS permanently gathers additional clinical data on the systems. This is done by studies (initiated by SIGNUS or by independent users), by monitoring databases in which problems with medical devices are reported, and by analyzing current scientific literature.

9 Alternatives to the use of posterior screw / rod systems

Generally, there are many alternatives to spinal instrumented fusion with SIGNUS posterior screw / rod systems.
We strongly recommend discussing possible alternatives with your spine surgeon or other doctors or healthcare professionals.

9.1 Alternative implants

There are many different posterior screw / rod systems on the market. Implants from respected spine companies typically show similar performances.

9.2 Alternative surgical treatments

Many pathologies can be fixated with other surgical methods (for example anterior or lateral implants) or no implants at all. The question of which treatment is best suited for a specific patient is highly debated and should be thoroughly discussed with your spinal surgeon.

9.3 Non-surgical treatment

Most patients are treated with non-surgical options (pain medication or physiotherapy) before surgery is considered. Specifically, if the goal of surgery is to reduce pain, non-surgical options should always be the first treatment. Surgery should only be considered once non-surgical treatment has failed.

10 Suggested training for users

Surgeries with spinal implants should only be performed by experienced spine surgeons specifically trained in the respective field.

11 Terms & Definitions and Abbreviations

Information for lay readers: The terms and definitions explained below may not be fully sufficient to understand the content of the document. If any information is unclear, please consult SIGNUS directly for details.

Table 10: Terms and definitions

Term	Definition
Adverse event	'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device; [Regulation (EU) 2017/745; Article 2 Definitions]
Bias	Bias is a systematic deviation of an outcome measure from its true value, leading to either an overestimation or underestimation of a treatment's effect. It can originate from, for example, the way patients are allocated to treatment, the way treatment outcomes are measured and interpreted, and the way data are recorded and reported. [Adapted from GHTF SG5/N2R8:2007]
Benefit-risk-determination	'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical benefit	'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health; [Regulation (EU) 2017/745; Article 2 Definitions]

Term	Definition
Clinical data	clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following: – clinical investigation(s) of the device concerned, – clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated, – reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated, – clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical evaluation	'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical evidence	'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
Clinical investigation	'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device [Regulation (EU) 2017/745; Article 2 Definitions] Systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device. Note: 'clinical trial' or ' clinical study' are synonymous with ' clinical investigation'. [EN ISO 14155:2011]

Term	Definition
Clinical performance	'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions] Behaviour of a medical device or response of the subject(s) to that medical device in relation to its intended use, when correctly applied to appropriate subject(s). [EN ISO 14155:2011]
Device registry	An organised system that uses observational study methods to collect defined clinical data under normal conditions of use relating to one or more devices to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves predetermined scientific, clinical or policy purpose(s). Note: The term "device registry" should not be confused with the concept of device registration and listing. [MEDDEV 2.12/2 rev2]
Feasibility study	A clinical investigation that is commonly used to capture preliminary information on a medical device (at an early stage of product design) to adequately plan further steps of device development, including needs for design modifications or parameters for a pivotal study. [MEDDEV 2.7/2 revision 2]
Hazard	Potential source of harm. [EN ISO 14971:2012]
Hazard due to substances and technologies	For the purpose of this MEDDEV document, a hazard that is seen with products that share specific characteristics. Note: This includes products that contain the same materials and substances, material combinations, use the same technologies, produce similar abrasion, are used with the same type of surgical approach, share the same manufacturing procedures or impurities, or share other characteristics. [MEDDEV 2.7/1 rev.4]
Incident	'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect; [Regulation (EU) 2017/745; Article 2 Definitions]

Term	Definition
Intended purpose	'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation; [Regulation (EU) 2017/745; Article 2 Definitions]
Instruction for use (IFU)	'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken; [Regulation (EU) 2017/745; Article 2 Definitions]
Performance	'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer; [Regulation (EU) 2017/745; Article 2 Definitions]
Post-market surveillance (PMCF)	'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;
PMCF plan	the documented, proactive, organised methods and procedures set up by the manufacturer to collect clinical data based on the use of a CE-marked device corresponding to a particular design dossier or on the use of a group of medical devices belonging to the same subcategory or generic device group as defined in Directive 93/42/EEC. The objective is to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence. [MEDDEV 2.12/2 rev.2]
PMCF study	A study carried out following the CE marking of a device and intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a device when used in accordance with its approved labelling. [MEDDEV 2.12/2 rev.2]
Risk	'risk' means the combination of the probability of occurrence of harm and the severity of that harm; [Regulation (EU) 2017/745; Article 2 Definitions] Combination of the probability of occurrence of harm and the severity of that harm. [EN ISO 14971:2012]
Risk management	Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk. [EN ISO 14971: 2012]

Term	Definition
Serious adverse event	'serious adverse event' means any adverse event that led to any of the following: (a) death, (b) serious deterioration in the health of the subject, that resulted in any of the following: (i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or prolongation of patient hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease, (c) foetal distress, foetal death or a congenital physical or mental impairment or birth defect; [Regulation (EU) 2017/745; Article 2 Definitions]
Serious Incident	serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat; [Regulation (EU) 2017/745; Article 2 Definitions]

Table 11: Abbreviations used in this CER

Abbreviation	Full word
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAPA	Corrective and preventive action
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
GSPR	General Safety and Performance Requirements
GTIN	Global Trade Item Number
MD	Mixed devices
MDCG	Medical Device Coordination Group
MDR	Medical device regulation
PMCF	Post-market clinical follow-up
PMS	Post market surveillance
PSUR	Periodic safety update
SD	Subject device
UDI	Unique Device Identification

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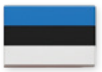
ET 	Kui vajate seda dokumenti mõnes Euroopa Liidu ametlikus keeles, saatke palun päring e-posti aadressil: info@signus.com
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