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IlluminOss™ Photodynamic Bone Stabilization System

SSCP Number	900694 Rev. A
SSCP Date Last Modified	01 MAY 2025
CER reference #	CER-1001

Summary of Safety and Clinical Performance (SSCP)
In accordance with EU MDR 2017/745, Article 32 and MDCG 2019-9



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PART A: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE – HEALTHCARE PROFESSIONAL SECTION

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

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

The following information is intended for users/healthcare professionals.

1. Device Identification and General Information

Device Identification and General Information	
Device Trade Name(s)	IlluminOss Photodynamic Bone Stabilization System
Manufacturer's name and Address	IlluminOss Medical, Inc. 993 Waterman Ave East Providence, RI 02914
Manufacturer's Single Registration Number (SRN)	US-MF-000003945
Basic UDI-DI	Photodynamic Polymer: ++M986MONOMERPH Photodynamic Bone Stabilization System Mini Sidefire (4x30mm - 8x80mm): ++M986MSSTRAIGHT6V Photodynamic Bone Stabilization System Sidefire Latitude (7mm x 160mm – 17mm x 280mm): ++M986SLSTRAIGHT7A Photodynamic Bone Stabilization System Sidefire Latitude (22/13mm x 160mm - 18/22mm x 90mm): ++M986SLTAPERED9 Photodynamic Bone Stabilization System Mini-Sidefire Latitude (6mm x 40mm - 9mm x 160mm): ++M986MLSTRAIGHTZR Photodynamic Bone Stabilization System Mini-Sidefire Latitude (13/10mm x 70mm - 13/10mm x 120mm): ++M986MLTAPERED9X
Medical Device Nomenclature Descriptions /Text	The IlluminOss Photodynamic Bone Stabilization System is a single use, sterile, intramedullary (IM) implant that provides an important treatment option in the fixation and stabilization of bone fractures through a minimally invasive procedure. The implant is sold as a kit that includes the implant (balloon catheter with light fiber) and other necessary items to complete the implantation of a particular size implant (sheath/dilator set, vented spike, liquid monomer vials, syringes, timer key, and IFU). An IlluminOss Photodynamic Light Curing System will be required to use the Implant. IlluminOss also offers



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Device Identification and General Information			
	reusable surgical instruments which may be used to perform more generic steps in this minimally invasive procedure.		
Class of Device	Class IIb per Rule 8 (Implant Kits and Photodynamic Monomer) - Implantable - non-WET		
EMDN Code		Implant Kits	Photodynamic Polymer
	EMDN Code	P09120201	P099001
	Code Description	BONE FIXATION NAILS, INTRAMEDULLARY	ORTHOPAEDIC CEMENTS
Year when the first certificate (CE) was issued covering the Device	2009		
Authorized Representative Name and SRN	Emergo Europe BV SRN: NL-AR-000000116		
Notified Body's name and the Notified Body's SIN	BSI Group The Netherlands B.V. SIN: 2797		

2. Intended Use of the Device

Intended Use	
Intended Purpose	The intended purpose of the Photodynamic Bone Stabilization System is to provide intramedullary fixation of bones.
Intended Users	Orthopedic surgeons
Intended Patient Population	Skeletally mature patients who experienced a fracture of the humerus (acute humerus fracture for patients over fifty), radius, ulna, clavicle, fibula, metacarpals, metatarsals, and phalanges, fragility fractures of the superior and inferior ramus of the pelvis, metastatic lesions in the pelvis, and/or fractures of the femur and tibia where another market-cleared fracture fixation system will be used.
Indications	The Photodynamic Bone Stabilization System is indicated for use in skeletally mature patients in treatment of fractures of the humerus, radius, ulna, clavicle, fibula, metacarpals, metatarsals, and phalanges. The IlluminOss System may be used in the treatment of fragility fractures of the superior and inferior ramus of the pelvis, as well as for the augmentation of metastatic lesions in the pelvis. The IlluminOss System may be used stand-alone or in conjunction with market-cleared fracture fixation systems to provide supplemental fixation in these anatomic sites.

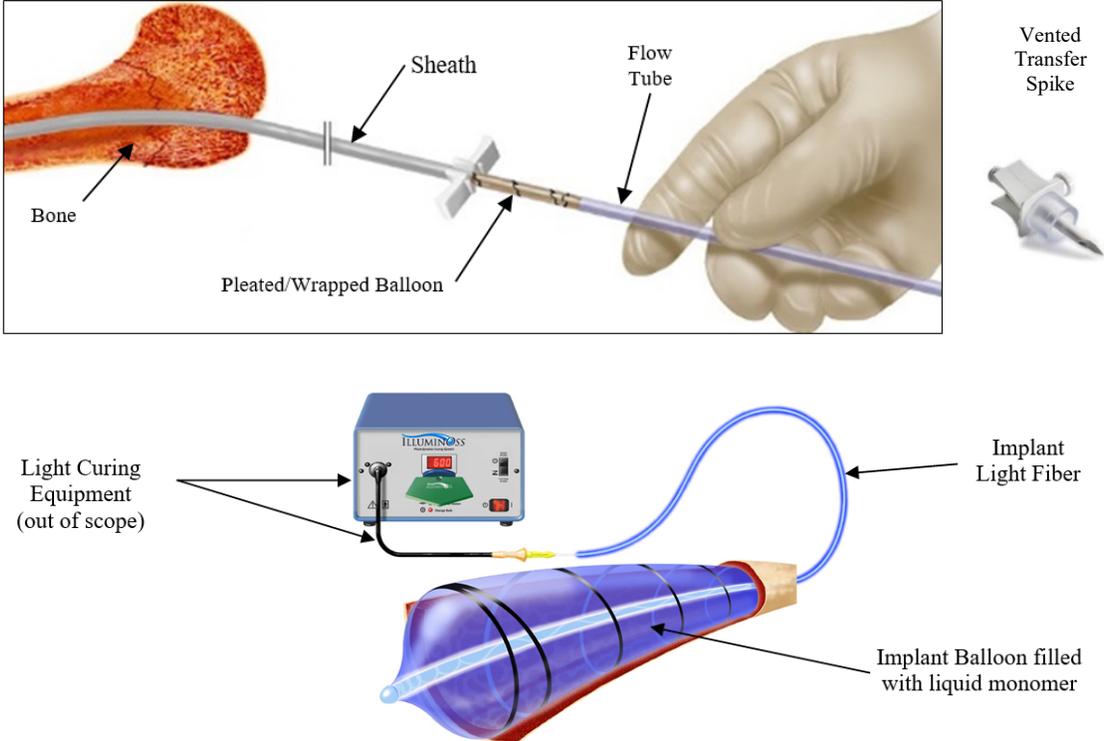


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Intended Use	
	The IlluminOss System may be used in the femur and tibia to provide supplemental fixation to an anatomically appropriate market-cleared fracture fixation system.
Contraindications and/or Limitations	<p>Contraindications</p> <p><u>For all bones:</u></p> <ul style="list-style-type: none"> • Patients who are considered skeletally immature. • Presence of active or incompletely treated infections that could involve the site where the device will be implanted. • Patients allergic to any of the implant materials, or to dental glue. • Patients whose intramedullary canal at site of fracture measures smaller than the diameter of the sheath provided. • Uncooperative patient or patient with neurologic disorder, incapable of following directions. • Distant foci of infections which may spread to the implant site. • Vascular insufficiency. • Open fractures with severe contamination. • Extremely comminuted fractures where insufficient holding power of the balloon on the intramedullary canal is probable. • Delivery sheath is unable to cross fracture site after proper fracture reduction and realignment. <p><u>For acute Humerus fractures:</u></p> <ul style="list-style-type: none"> • Patients who are under the age of Fifty (50) <p><u>For all bones excluding pathologic lesions:</u></p> <ul style="list-style-type: none"> • Metabolic disorders which may impair bone formation. • Osteomalacia. • Vascular insufficiency, muscular atrophy, or neuro-muscular disease <p>Limitations</p> <p>N/A - IlluminOss has captured any limitations for use of the device within our indications (bone specific), as well as contra-indications (patient selection), and warnings/precautions (use considerations). IlluminOss has not identified any other limitations for the device use, when used per the instructions for use.</p>

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3. Device Description

Device Description	
Description of the Device	<p>This document covers the single use, sterile, intramedullary (IM) implant known as the IlluminOss Photodynamic Bone Stabilization System. The implant is part of a kit which includes the implant (balloon catheter with light fiber) and other necessary items to complete the implantation (sheath/dilator set, timer key, vented spike, liquid monomer vials, syringes, IFU & labelling) of a particular size implant (See Figure). The balloon catheter with light fiber, vented spike (used to complete the transfer of liquid monomer from a vial into a syringe), liquid monomer & syringes are all provided sterile. The implant design includes two variations described as larger profile (LP) implants and smaller profile (SP) implants, where relative profile size refers to the diameter sizes of the light fibers used in fabrication (1.5mm and 1.00mm), the diameter of the flex catheter (2.8mm and 4.4mm), and the diameter of the tear-away sheath (and resulting bone hole) (3.5mm/4.5mm and 5.2mm/7.0mm) that is required to deliver the implant safely within the IM canal.</p> <p style="text-align: center;">Photodynamic Bone Stabilization System Images</p>  <p>The image block contains two diagrams. The top diagram shows a hand holding a device with labels: 'Bone' (pointing to a bone cross-section), 'Sheath' (pointing to a grey tube), 'Flow Tube' (pointing to a blue tube), and 'Pleated/Wrapped Balloon' (pointing to a blue balloon on the device). To the right is a 'Vented Transfer Spike' (a small metal tool). The bottom diagram shows 'Light Curing Equipment (out of scope)' connected to an 'Implant Light Fiber' (a blue fiber) which is inserted into an 'Implant Balloon filled with liquid monomer' (a blue balloon on a device).</p> <p>IlluminOss Intramedullary Implants are designed to stabilize bone fractures to help promote the healing process. During a fracture stabilization surgical procedure in the operating room (OR),</p>



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Device Description																									
	<p>Implants are inserted through a prepared bone hole and into the cleared IM canal, leaving the balloon portion across a reduced fracture. The Implant is then infused with a proprietary liquid monomer, filling and expanding the balloon portion of the implant. The end-connector of the implant's light fiber connects into the gold connector of the Light Guide, a part of the IlluminOss Photodynamic Light Curing System. The Photodynamic Light Curing System is used to generate and deliver visible blue light to IlluminOss implants for the purpose of curing (aka, hardening or polymerizing) the proprietary liquid monomer that has been used to fill the balloon portion of the implant. The monomer filled balloon is cured in-situ resulting in a permanent implant. After completing the cure cycle, the catheter portion is separated from the balloon leaving the implant to stabilize the fracture during the healing process.</p> <p>The Implants are offered in a variety of sizes. The choice of which size implant a surgeon may wish to use to treat a given bone lies with the surgeon, following the instructions for use to select the balloon size that corresponds to the bone canal diameter and length. IlluminOss Implants may be used as a stand alone device or in conjunction with cleared fracture fixation systems (e.g., plates, screws, nails etc.) to provide supplemental fixation. For example, the IlluminOss implant may not be the primary stabilization device and may be used to augment primary internal fixation.</p>																								
List of Previous generation(s) or variants if such exist, and a description of the differences.	<p>The balloons used for the proposed application are straight and/or tapered to accommodate the canal (straight balloon) or the canal and head (tapered balloon) of the treated bone, depending on the target location of placement. In addition, balloons are available in various lengths and diameters to accommodate different anatomies. Depending on the balloon size, an appropriate amount of monomer in 20ml vials, and two or three 20cc syringes is provided for the convenience of the user.</p> <p>Previous Device generations:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Date (EU)</th> <th style="width: 60%;">Description of Change</th> <th style="width: 25%;">Reason for Change</th> </tr> </thead> <tbody> <tr> <td>March 2009</td> <td>Initial Launch – targeting use in the Hand and Clavicle</td> <td>Initial Launch</td> </tr> <tr> <td>February 2010</td> <td>To support further indications (low load bearing bones)</td> <td>New indications</td> </tr> <tr> <td>July 2012</td> <td>Introduction of the Vented Transfer Spike</td> <td>Product Improvement</td> </tr> <tr> <td>October 2014</td> <td>Introduction of a new molded Y Connector for all implants</td> <td>Product Improvement</td> </tr> <tr> <td>July 2015</td> <td>Introduction of Balloon Radiopaque Marking for all implants (Supplier Micropen)</td> <td>Product Improvement</td> </tr> <tr> <td>July 2019</td> <td>Expansion for use in the Humerus - pathologic</td> <td>New Indication</td> </tr> <tr> <td>April 2021</td> <td>Expansion for use in the Humerus - acute</td> <td>New Indication</td> </tr> </tbody> </table>	Date (EU)	Description of Change	Reason for Change	March 2009	Initial Launch – targeting use in the Hand and Clavicle	Initial Launch	February 2010	To support further indications (low load bearing bones)	New indications	July 2012	Introduction of the Vented Transfer Spike	Product Improvement	October 2014	Introduction of a new molded Y Connector for all implants	Product Improvement	July 2015	Introduction of Balloon Radiopaque Marking for all implants (Supplier Micropen)	Product Improvement	July 2019	Expansion for use in the Humerus - pathologic	New Indication	April 2021	Expansion for use in the Humerus - acute	New Indication
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Device Description	
List and Description of any Accessories which are intended to be used in combination with the device	N/A - There are no other products sold separately as accessories to the Photodynamic Bone Stabilization System, where accessory is understood as an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).
Description of medicinal substances, or substances of animal origin or their derivatives	N/A - There are no medicinal substances or pharmaceutical components incorporated into this device. The device does not incorporate any substances of animal origin or their derivatives. This device does not incorporate any blood components.
Description of any other devices and products which are intended to be used in combination with the device	<p>The IlluminOss device uses a photodynamic liquid monomer which provides the surgeon with a great amount of flexibility during the fixation procedure as it cures on demand and only upon the application of light emitted from a specialized source (Gausepohl et al., 2017). These resins require an activating agent to initiate the polymerization process. When the supplied light system is activated, it triggers the photo initiator solution within the liquid monomer which then rapidly polymerizes and hardens in situ.</p> <p>In order to initiate polymerization, the IlluminOss Implant is used with the Photodynamic Light Curing System which includes a light source console, fiber optic light guide, foot pedal, power cord, and optional pole clamp. This unit has been designed to operate outside of the surgical field. The console consists of an aluminum housing containing a 75W, medium pressure arc metal halide lamp which is mounted in a reflector and focused to provide optimum light output. This device is designed to emit visible blue light (400 - 450nm) which, as previously stated, causes the light curable monomer to polymerize and cross-link. The result is a biocompatible cross-linked, thermoset polymer. The Photodynamic Light Curing System is necessary for completing the process of implant curing when using an IlluminOss Photodynamic Bone Stabilization System implant; therefore, there are no alternative options that may be used.</p> <p>The use of instruments in a given surgical procedure is typically not optional. While the IlluminOss instruments are designed to be exclusively used with the corresponding implant system, other instruments, such as guidewires, are more general with a variety of potential applications (not implant specific). The only choice that likely exists for a surgeon is the</p>



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Device Description	
	<p>selection of a particular instrument or size variant, not whether an instrument should be used at all. This selection process is typically dictated by the specific surgical procedure being utilized as well as the implant system itself. Other influencing factors on instrumentation includes availability and surgeon preference. Accordingly, instruments are less a surgical option than a surgical necessity. It is important to emphasize that the IlluminOss light source and instruments are an indispensable part of the surgical process and are used in various situations, including preparation and placement of the IlluminOss implant.</p> <p>Unlike traditional metallic IM nailing implants, the IlluminOss implants use a non-compliant PET balloon and photodynamically cured monomer to achieve implant rigidity for treatment of bone fractures. Consequentially, the system requires surgical instruments for implant delivery and removal as well as a light source to deliver and cure the liquid monomer in situ. There are a variety of reusable instruments to assist the surgeon with the implantation and/or removal procedure when, in their operation, other hand tools may not be convenient. The instrumentation includes awls, drill bits, T-handles, guide wires, flexible reamers, burrs, flexible stabilizer and stabilizer tubes, catheter separator (used to separate the cured IM rod from the catheter), hooks, and slap hammers. These types of instruments are commonly utilized in surgical procedures associated with alternative treatments for fracture fixation such as traditional IM nailing and internal fixation with plate and screw systems.</p> <p>Further, because the IlluminOss implant is delivered through a minimally invasive percutaneous approach, the system also includes single-use instruments intended for use during implantation and monomer infusion. These single-patient access and implant delivery instruments include cannulas, introducer sheaths, dilators, air evacuation and monomer delivery syringes, and balloon delivery catheters. While these types of instruments are not typically used during most internal fixation procedures associated with the alternative therapies, they are commonly utilized in other surgical procedures, such as vertebral kyphoplasty, where they have demonstrated long-term clinical success. The IlluminOss device is inflated with the photocurable monomer which cures in situ and is then maintained within the delivery balloon.</p>

4. Risks and Warnings

Risks and Warnings	
Residual risks and undesirable effects	<p><u>Risks</u></p> <p>For all bones</p> <p>As with any IM fixation system or rod the following can occur:</p> <ul style="list-style-type: none"> loosening, bending, cracking or fracture, or mechanical failure of the components or loss of or inadequate fixation in bone attributable to delayed union, nonunion, insufficient quantity

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Risks and Warnings

	<p>or quality of bone or markedly unstable comminuted fractures, or insufficient initial fixation,</p> <ul style="list-style-type: none"> • loss of anatomic position with nonunion or malunion with rotation or angulation • adverse tissue reaction, • infection, including wound complications, • thromboembolic event or fat embolism (blood clot, fat, or other material that could result in organ damage or failure), • implantation-related bone fracture, • soft tissue damage, • pain and/or loss of function, revision, • inability to properly deploy or remove device. <p>Specific to a photodynamic curing system the following can occur:</p> <ul style="list-style-type: none"> • lack of electrical safety or electromagnetic compatibility, • unacceptable exothermic reaction, • balloon leakage. <p>The identified risks were quantified when the device was used as intended with reference to the type of data sources used to assess risk level. Unless noted, these events are considered events related to the device.</p>																																																
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Risks and Warnings				
	Screw Dislocation	4.6%	1.7% (1 event)	NR
	Inadequate Fixation/ Loss of Fixation	0.9%	NR	0.03%
	Packaging Damage	NR	NR	0.03%
<p>NR=Not Reported *Higher events were related to the use of the device in the pathological population.</p> <p>Other event types were reported in low numbers in minimal studies. None were considered unanticipated given the population, procedure-type, or device-type. PMS data captures events intra-operatively or post-operatively that occurred more than once.</p>				
Warnings and precautions	<p>Warnings</p> <ul style="list-style-type: none"> ⚠ Do not reuse or attempt to re-sterilize the disposable components, doing so may result in injury or death. ⚠ Discard and do not use opened or damaged packages. Do not use if there is a loss of sterility of the monomer or other kit components. ⚠ Do not utilize any component after the expiration date. ⚠ Correct selection of the implant diameter and length is extremely important. Before implantation: <ul style="list-style-type: none"> ⚠ Ensure the implant is long enough to span the fracture, and is not longer than the canal. ⚠ Ensure that the implant diameter is large enough to ensure cortical contact. ⚠ Ensure the separation instrument can reach the balloon. ⚠ The polymerization (curing cycle of implant) is a short-term exothermic reaction. ⚠ Do not insert or affix sutures, K-wires, or other hardware to or through the stabilization balloon until cured, nor bring sharp objects in contact with the balloon until cured (e.g. screws, plates, etc.). Do not apply instruments or clamps onto the stabilization balloon until cured. ⚠ Do not attempt to inflate the balloon catheter by use of any ancillary inflation equipment. Properly sized inflation syringes and the amount of polymer necessary to accomplish the appropriate inflation are provided. The balloon is made of a non- 			



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Risks and Warnings	
	<p>compliant, thin walled PET and does not expand larger than its prescribed size.</p> <ul style="list-style-type: none"> ⚠ Do not add any material or fluids to the polymer. ⚠ Do not expose polymer to any light source other than the IlluminOss Photodynamic Curing System, shield polymer from light after removal from vial. ⚠ Do not severely bend or kink the light fiber, catheter or balloon implant. Handle the components with care. Severe bends or kinks in the implant assembly will substantially reduce the light intensity delivered to the implant causing incomplete hardening of the liquid monomer. ⚠ If, upon fluoroscopic examination, the user determines that the inflated balloon is not in contact with the intramedullary canal of the bone, the user should remove the balloon prior to curing the polymer, reassess sizing, and replace it with the appropriately sized balloon. ⚠ Do not activate the light source until the balloon catheter is in the appropriate position and the bone fracture is reduced and ready for stabilization. Activation of the light source in the presence of the monomer will initiate polymerization, an irreversible process. ⚠ The polymer must be exposed to the IlluminOss Photodynamic Curing System for a specific amount of time in order to activate and fully cure the implant. A partially cured implant cannot be used to complete a procedure. If an uncured, or partially cured implant is suspected, or if a curing cycle is interrupted, additional curing cycles should be completed. ⚠ Inadequate postoperative fixation or unanticipated postoperative events may affect the interface between the bone and stabilization balloon, which may lead to micro-motion of the implanted balloon and balloon surface. Periodic follow up examinations and radiographs are advised for all patients. ⚠ Deep wound infection is a serious postoperative complication and may require total removal of the stabilization system and embedded polymer. Deep wound infection may be latent and not manifest itself for several years post- operatively. <p><u>Precautions</u></p> <ul style="list-style-type: none"> • Read instructions prior to use.



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Risks and Warnings

	<ul style="list-style-type: none"> • Prior to using the IlluminOss Photodynamic Bone Stabilization System, surgeons should, through specific training and experience, be thoroughly familiar with the properties, handling characteristics, and application of the system. • Strict adherence to good surgical principles and technique are required during the use of the IlluminOss Photodynamic Bone Stabilization System. • The polymer in liquid form may cause sensitization by skin contact. In case of contact with skin, wash immediately with soap and water. • In the tibia and femur, the IlluminOss implant is intended only as a means of providing supplemental fixation for EU-cleared fracture fixation devices. In the tibia and femur, IlluminOss cannot be used as a stand-alone implant.
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<p>Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable</p>	<p>Field Safety Corrective Actions: None.</p> <p>Field Safety Notices: None.</p> <p>Although not subjected to any field safety corrective actions (action taken for technical or medical reasons to prevent or reduce the risk of serious incident in relation to this device), the manufacturer has implemented the following actions within the past 13 years in response to observed field performance, in order to maintain the risk profile of the device:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Ref. #</th> <th style="width: 10%;">Date</th> <th style="width: 60%;">Description</th> <th style="width: 20%;">Status</th> </tr> </thead> <tbody> <tr> <td>CAPA-1077</td> <td>2018</td> <td>In response to 2 complaints where implants have been damaged after placement in the patient, this CAPA was initiated to investigate. The most probable root cause of the damage was the user attempting to reduce the fracture with a clamp after the placed balloon was infused with liquid monomer, prior to complete curing. The IFU and surgical technique guides provided instruction to remove liquid monomer from the implant prior to re-positioning, along with a warning to not contact the balloon with hardware until fully cured. Action was taken to supplement these existing user materials with additional revision-controlled surgeon training materials.</td> <td>Complete</td> </tr> <tr> <td>CAPA-1102</td> <td>2019</td> <td>In response to a complaint investigation into the root cause of a light fiber break that caused the failure of the monomer inside an implanted balloon catheter to fully cure, this CAPA was initiated. Additional clarity was added in the Surgeon's Technique Guide to ensure that users do</td> <td>Complete</td> </tr> </tbody> </table>	Ref. #	Date	Description	Status	CAPA-1077	2018	In response to 2 complaints where implants have been damaged after placement in the patient, this CAPA was initiated to investigate. The most probable root cause of the damage was the user attempting to reduce the fracture with a clamp after the placed balloon was infused with liquid monomer, prior to complete curing. The IFU and surgical technique guides provided instruction to remove liquid monomer from the implant prior to re-positioning, along with a warning to not contact the balloon with hardware until fully cured. Action was taken to supplement these existing user materials with additional revision-controlled surgeon training materials.	Complete	CAPA-1102	2019	In response to a complaint investigation into the root cause of a light fiber break that caused the failure of the monomer inside an implanted balloon catheter to fully cure, this CAPA was initiated. Additional clarity was added in the Surgeon's Technique Guide to ensure that users do	Complete
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Risks and Warnings			
			not bend or use excessive force on light fibers while handling throughout the implantation and curing phases of the procedure.
	CAPA-1119	2021	A preventive action was implemented in response to ongoing monitoring of the rate of post-operative implant breaks due to patients unable to follow instructions, lack of balloon contact with the cortical wall upon placement, and insufficient quality or quantity of bone. Although the product still performed within its anticipated risk profile for these hazardous situations, this preventive action was initiated to maintain the hazards' occurrence rates within that anticipated risk profile. Additional information that correlated the potential hazard with the already existing IFU warnings/risk/precautions was generated to supplement Surgical Technique Guides and internal sales training.
	CAPA-1128	2021	In response to customer complaints into the root cause of implants regarding draw of a vacuum during implant preparation, this CAPA was initiated. Corrective Action was taken to introduce additional manufacturing controls, along with additional component inspections to prevent this issue from recurring.

5. Summary of Clinical Evaluation and Post-Market Clinical Follow-up (PMCF)

Data are available on over 2,700 fractures across the four completed clinical investigations and published literature. The evidence covers all of the indications, reporting on both safety and performance during the time of bone healing. Additionally, there have been over 9,000 devices sold since January 2011 with no unacceptable side-effects identified, as well as no field safety notices or recalls. A breakdown of evidence, including clinical literature, is provided in **Table 1**.

Table 1: Summary of Clinical Evidence

Indication / Anatomical Location	Number of Fractures/Patients	
	Clinical Investigation	Literature
Overall	413	>2,551
Treatment of Fractures of the Humerus, Radius, Ulna, Clavicle, Fibula, Metacarpals, Metatarsals, and Phalanges	344	>1,849
Treatment of Fragility Fractures and Metastatic Lesions of the Pelvis	22	561
Treatment in the Femur and Tibia as Supplemental Fixation	46	137
Off-Label		
Sternum	1	4



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5.1 Summary of clinical data related to equivalent device, if applicable

Not applicable

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

CE Marking Study of the IlluminOss Photodynamic Bone Stabilization System for the Treatment of Humerus Fractures

A study, "CE Marking Study of the IlluminOss Photodynamic Bone Stabilization System for the Treatment of Humerus Fractures" (Protocol #: 12-03-EUHUM-01), was conducted to collect safety and performance data on the use of the IlluminOss System when used to provide stabilization and alignment for the treatment of acute humerus fractures. The study population consisted of skeletally-mature adult patients with a single, acute, isolated humerus fracture. The study was a prospective, multi-center, open label study with a total duration of approximately 24 months, including the enrollment period. The primary endpoint is the assessment of normal radiographic fracture healing determined at the Day 180 Visit. Normal radiographic healing was defined by 2 of 4 cortices or 2 of 4 views demonstrating bridging on standard radiographs.

The secondary safety endpoints, evaluated at the Day 180 and Day 360 Visits, include:

- Assessment of the incidence of AEs
- Assessment of the procedure- and device-related complication rate

The secondary performance endpoints include:

- Evaluation of complete radiographic healing at the Day 180 Visit, defined as 3 of 4 cortices or 3 of 4 views demonstrating bridging, with dissolution of the majority ($\geq 75\%$ on orthogonal views) of fracture lines
- Evaluation of normal radiographic healing at the Day 360 Visit
- Evaluation of complete radiographic healing at the Day 360 Visit, defined as 3 of 4 cortices or 3 of 4 views demonstrating bridging, with dissolution of the majority ($\geq 75\%$ on orthogonal views) of fracture lines
- Identification of duration of index procedure and length of hospital stay
- Assessment of no pain at palpation status
- Assessment of return to pre-fracture mobility status
- Comparison of pain visual analog scale from baseline to all follow-up intervals
- Comparison of Disability of the Arm, Shoulder, and Hand score from baseline to all follow-up intervals
- Comparison of Constant Shoulder score from baseline to all follow-up intervals
- Assessment of range of motion
- Assessment of disability status
- Assessment of return to work status

In addition to disability and return to work status, the following health economic data are analyzed:

- Evaluation of duration of physical therapy prescription
- Assessment of the use of supportive orthopedic devices post-surgery
- Assessment of prescription and over-the-counter analgesic medication use

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For the ITT population (33 patients), the proportion of patients with valid assessments who were confirmed to have normal radiographic healing of their fracture at the Day 180 Visit was 96%. For the mITT population (44 patients), the proportion of patients with valid assessments who were confirmed to have normal radiographic healing of their fracture at the Day 180 Visit was 94%.

For the ITT population, 96.3% of 27 patients who were assessed did not report any pain on palpation by the Day 180 Visit. At the Day 360 Visit, 96.4% of the 27 patients assessed reported no pain on palpation. The majority of patients who did report pain, reported it as being mild. Results were similar for the mITT population.

At the Day 180 Visit, the mean DASH score was 30.629 compared to a mean baseline DASH score of 65.540, a mean change from baseline of -35.996. At the Day 360 Visit, the mean DASH score was 23.908 compared with a mean change from baseline of -42.717. Overall, the mean DASH scores for the ITT population improved over time. Results were similar for the mITT population.

At the Day 180 Visit, the mean Constant Shoulder score was 43.693 compared to a mean baseline score of 22.86; with a mean change from baseline of 22.869. At the Day 360 Visit, the mean Constant Shoulder score was 48.147 with a mean change from baseline of 27.324. Results were similar for the mITT population.

The mean active range of motion scores for abduction, flexion, extension, lateral rotation, and medial rotation of the affected arm of patients in the ITT population increased at each study visit. Results for the mITT population were similar.

The mean passive range of motion scores for abduction, flexion, extension, lateral rotation, and medial rotation of the affected arm of patients in the ITT population increased slightly from the Day 7 to the Day 360 Visit. Results were similar for the mITT population.

There were no unanticipated adverse device effects (UADEs) or serious UADEs reported. A summary of procedure- and device-related adverse are provided below.

Thirty-three events in 16 patients (36.4%) were classified as related to the procedure.

Table 2: Procedure-Related Adverse Events

Event (Preferred Term)	Number of Events	%
Wound Secretion	3	6.8%
Device Extrusion	2	4.5%
Implant Site Reaction	2	4.5%
Joint Dislocation	2	4.5%
Musculoskeletal Pain	2	4.5%
Pain in Extremity	2	4.5%
Anemia	1	2.3%
Arthritis Infective	1	2.3%

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Event (Preferred Term)	Number of Events	%
Bone Fragmentation	1	2.3%
Bone Pain	1	2.3%
Confusional State	1	2.3%
Decubitus Ulcer	1	2.3%
Device Breakage	1	2.3%
Device Dislocation	1	2.3%
Diarrhea	1	2.3%
Implant Site Reaction	1	2.3%
Joint Swelling	1	2.3%
Localised Oedema	1	2.3%
Musculoskeletal Stiffness	1	2.3%
Oedema Peripheral	1	2.3%
Peripheral Swelling	1	2.3%
Post-Procedural Hematoma	1	2.3%
Pseudarthrosis	1	2.3%
Pyrexia	1	2.3%
Resorption Bone Increased	1	2.3%
Rotator Cuff Syndrome	1	2.3%

Only 5 (11.4%) TEAEs were classified as ‘possibly related’ to the device; no events were classified as ‘definitely related’ to the device. Three of these events were considered to be an SAE. A description of these 5 events is provided below:

- 1 device dislocation was reported related to a translation error during implantation where the PBSS implant was utilized with one screw. It is important to note, the implant did not “dislocate” though this was the AE category assigned by the site. The implant remained in place, but the head of the humerus moved medially.
- 1 delayed fracture union occurred in the population where the PBSS was used with a single screw. This delayed union led to secondary device breakage.
- 2 screw dislocations occurred in cases where plates and screws were used in conjunction with the PBSS implant. In both cases, the surgeon missed delivering the screw into the IlluminOss implant.

Three (6.8%) of the events led to secondary surgery (1 device dislocation and 2 screw dislocations).

The study concluded that the IlluminOss Photodynamic Bone Stabilization System is safe and effective for the treatment of acute, single, isolated humerus fractures in skeletally mature adults.

This study was published by Vegt, et al. in the following publication:

Vegt P, Verbruggen J, Gausepohl T, et al. (2018). The Photodynamic Bone Stabilization System in the Treatment of Humerus Fractures: A Prospective Clinical Trial. Cureus 10(6): e2809. doi:10.7759/cureus.2809



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5.3 Summary of clinical data from other sources, if applicable

EU Registry

Following CE marking in 2009 for use in the metacarpal, phalange, clavicle, radius, ulna, distal radius, olecranon, fibula, a registry study was subsequently initiated in Europe with the aim of collecting technical and clinical outcomes on patients treated with the IlluminOss Photodynamic Bone Stabilization System.

The EU Registry for the IlluminOss Photodynamic Bone Stabilization System was initiated in September 2010. Up to 200 subjects were to be followed either until they were discharged from clinical care, or were followed for up to two years post index surgery. There were no specified procedures or follow up intervals for patients who enrolled into the registry. Standard of care demographic and fracture-related data, including radiographs, were entered into a web-based database by hospital personnel. The database prospectively queried for the incidence of adverse device effects. Radiographs from subjects who have been followed for 12 months post treatment were independently reviewed to assess radiographic safety and healing parameters.

A total of 149 fractures were treated in 132 enrolled patients at multiple centers in Germany and the Netherlands. The study was designed to review the device in the approved indications of low-load bearing anatomic locations; however, the humerus, femur, tibia, and pelvis were also treated under compassionate use guidelines.

The results related to the IlluminOss System EU Registry are included in the publication:

Gausepohl, T., Pennig, D., Heck, S., Gick, S., Vegt, P. A., & Block, J. E. (2017). Effective management of bone fractures with the IlluminOss® photodynamic bone stabilization system: initial clinical experience from the European Union registry. *Orthopedic reviews*, 9(1).

Additional manufacturer-held data are available for the subject device when used to treat pathological humerus fractures (indication CE marked in July 2019).

It is important to note, the goals of surgical treatment for patients with pathological impending or actual fractures is to relieve pain, restore function, and optimize the quality of life remaining in the patients. The clinical expectation of significant bone healing cannot be expected. This patient population has an extremely high mortality rate which can be as high as 80% after one year. Given the high mortality rate and clinical goal to improve the patients' remaining quality of life, shorter evaluation time points than a typical fracture fixation study were evaluated to assess the effectiveness and clinical benefit of the IlluminOss System.

US Study - A Prospective, Multi-center Study of the IlluminOss® Photodynamic Bone Stabilization System for the Treatment of Impending and Actual Pathological Fractures in the Humerus from Metastatic Bone Disease. This study was a prospective, multi-center open label study of 81 subjects implanted with the IlluminOss System for the treatment of impending and actual pathological fractures in the humerus from metastatic bone disease. Follow up visits occurred at 7, 30, and 90 days which is the primary endpoint, with extended follow-up visits occurring at 180 and 360 days following surgery. Subjects were monitored over the study period to evaluate for pain, functional outcomes and safety parameters which included no additional surgical interventions and the occurrence of other adverse device effects. Device- and Procedure- Related Adverse Events were minimal and anticipated (n = 32). The incidence of second surgeries was also low with only five subjects receiving a second surgery related to the device.

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No bone infections were observed and only one wound site infection occurred in the study. None of the safety data resulted in the identification of new or emerging risks related to the IlluminOss System.

Table 3: Summary of Device- and Procedure-Related AEs

Adverse Event	N	%	Severity	SAE
Device-Related (n=12 events / 6 patients)				
Device Breakage	2	2.5%	Severe	Yes (n=6)
Device Breakage	7	8.6%	Moderate	
Medical Device Site Pain	3	3.7%	Moderate	Yes (n=2)
Procedure-Related (n=20)				
Medical Device Site Pain	2	2.5%	Moderate	No
Radial Nerve Palsy	1	1.2%	Moderate	No
Haemorrhagic Anaemia	1	1.2%	Moderate	No
Peripheral Swelling	1	1.2%	Moderate	No
Medical Device Site Swelling	2	2.5%	Mild	No
Haemoglobin Decreased	2	2.5%	Mild	No
Peripheral Swelling	1	1.2%	Mild	No
Hypersensitivity	1	1.2%	Mild	No
Urinary Tract Infection	1	1.2%	Mild	No
Wound Infection	1	1.2%	Mild	No
Post-Procedural Discomfort	1	1.2%	Mild	No
Procedural Complication	1	1.2%	Mild	No
Arthralgia	1	1.2%	Mild	No
Bone Pain	1	1.2%	Mild	No
Musculoskeletal Stiffness	1	1.2%	Mild	No
Endotheliomatosis	1	1.2%	Mild	Yes (n=1)
Paraesthesia	1	1.2%	Mild	No

www.clinicaltrials.gov – Identifier: NCT02338492

EU Study - A Prospective, Multi-center Study of the IlluminOss® Photodynamic Bone Stabilization System for the Treatment of Impending and Actual Pathological Fractures in the Humerus from Metastatic Bone Disease. Under the same study design as the US Study above, 14 patients were enrolled in European sites (i.e., Austria, Germany, and the Netherlands). This study was an open label, single arm study enrolling subjects with impending and actual fractures of the humerus secondary to metastatic bone disease. Following successful placement of the Photodynamic Bone Stabilization System, subjects were evaluated for safety and effectiveness of the device at 7, 30, 90, 180, and 360 days post-index procedure. Subjects were monitored over the study period to evaluate for pain, functional outcomes and safety parameters which included no additional surgical interventions and the occurrence of other adverse device effects. Among the 14 subjects in the safety population, ten subjects (71.4%) had a TEAE, no subject had a device-related TEAE, and no subject had an Unexpected Adverse Device Effect (UADE). Five of the nine subjects in the ITT Population died of progression of the underlying cancer. Ten enrolled subjects experienced 20 SAEs.



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www.clinicaltrials.gov – Identifier: NCT02373904

The data from the pathological humerus studies did not identify any unanticipated events for the patient population or emerging safety data.

Clinical Literature Search Results (through December 2024)

Overall, the reviewed literature for this CER included 72 studies reporting over 2,480 subjects treated with the IlluminOss device.

The reviewed literature shows the device is effective and safe when used as intended for use in skeletally mature patients in the treatment of traumatic, fragility, pathological, and impending pathological fractures of the humerus, radius, ulna, fibula, metacarpals, metatarsals, and phalanges. Additionally, the reviewed literature demonstrated safety and effectiveness for the IlluminOss System in the treatment of fragility fractures of the superior and inferior ramus of the pelvis, as well as for the augmentation of metastatic lesions in the pelvis and in the femur and tibia to provide supplemental fixation to an anatomically appropriate market-cleared fracture fixation system.

The IlluminOss device achieves the principal benefit of bone fixation, achieved by bone healing or union (>94% in the clinical studies and mean 97.4% in the clinical literature), while secondary benefits include patient-reported outcomes indicative of healing (i.e., improvement in pain and function). Similarly, safety data collected from the clinical literature supports that the subject device is safe when used in accordance with the intended use. A limited number of adverse events were reported in the literature. A summary of the evidence by each indication is provided below:

Key Performance Parameter: Bone Healing	Key Safety Parameters		
	Non-Union	Secondary Surgery	Device Failure
Overall: 97.4%	Overall: 0.5%	Overall: 2.2-2.9%	Overall: 3.3%
Humerus: 91.6%*	Humerus: 1.0%	Humerus: 3.3-3.5%	Humerus: 6.5%*
Radius/Ulna: 100%	Radius/Ulna: 0.0%	Radius/Ulna: 1.2-1.3%	Radius/Ulna: 3.2%
Fibula: 100%	Fibula: 0.0%	Fibula: 1.0-1.7%	Fibula: 3.9%
Metacarpals, Metatarsals, Phalanges: 100%	Metacarpals, Metatarsals, Phalanges: 0.0%	Metacarpals, Metatarsals, Phalanges: 0.6-1.7%	Metacarpals, Metatarsals, Phalanges: 3.9%
Pelvis: 96%	Pelvis: 0.3%	Pelvis: 2.3-2.4%	Pelvis: 2.7%
Femur/Tibia: 100%	Femur/Tibia: 0.0%	Femur/Tibia: 1.6-1.7%	Femur/Tibia: 3.8%

*Lower rates of bone healing and higher rates of device failure were related to the use of the device in the pathological population.

In conclusion, clinical data from the included studies demonstrate the acceptable performance and safety of the subject device when used as intended relative to the state of the art, thus supporting conformity to the relevant essential requirements and general safety and performance requirements.



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5.4 An overall summary of the clinical performance and safety

The probable benefits of the IlluminOss Photodynamic Bone Stabilization System are based on data from pre-market clinical investigations and published literature. The benefits of using the IlluminOss Photodynamic Bone Stabilization System for the treatment of bone fractures include the key performance parameter of bone union, as well as improvement in pain and function.

In the premarket humerus study overall, patients showed complete healing in 96% of the ITT and mITT populations at 1 year post-operatively. Healing was associated with both a decrease in pain (improvement in VAS score of 50.2mm) and function (improvement in DASH score of 43.850). Additionally, reported complications were not unanticipated in type or occurrence based on the identified State of the Art patient population. These results are substantiated by supported evidence from the EU registry data, published literature of over 2,500 patients, and real-world post-market surveillance data of over 9,000 implants in 13 years.

Compared to the alternative treatment option of metal IM nails, internal fixation with plates and screws and cementoplasty, the IlluminOss Photodynamic Bone Stabilization System is comparable in the rate of bone healing to the State of the Art treatment options. The IlluminOss System also give surgeons increased screw placement options as the screws can be drilled directly into the IlluminOss implant versus metal IM Nails which are restricted to placing screws in the manufactured screw holes. Non-clinical testing has demonstrated that screws implanted into the IlluminOss implant have increased pull-out strength, and the placement of screws into the IlluminOss implant do not impact the mechanical performance of the implant. These data are further supported by the clinical evidence demonstrating no statistically significant differences in healing between patients receiving the IlluminOss implant alone with or without screws compared to the IlluminOss implant used with plates and screws.

The safety and side-effect acceptability of the IlluminOss System has been demonstrated by an evaluation of the key safety parameters compared to the State of the Art and an assessment of the consistency of the identified risks with the risk documentation and IFU. The IlluminOss System is in line with the State of the Art in rates of non-union, secondary surgery, and implant failure. All other risks identified in the literature for CE marked indications and non-CE marked indications were anticipated per the device risk documentation and IFU.

An evaluation of the non-clinical data, pre-market clinical data, registry data, published literature, and post-market surveillance data demonstrate the IlluminOss Photodynamic Bone Stabilization System is safe and performs as intended. The known risks have been adequately mitigated through non-clinical testing (bench testing, biocompatibility, sterility, and shelf-life) and device labeling, including both package labeling and surgical technique guides. The compiled clinical evidence and real world post market experience demonstrate the benefits of the IlluminOss Photodynamic Stabilization System outweigh the risks.

5.5 Ongoing or planned post-market clinical follow-up

The focus of the IlluminOss Photodynamic Bone Stabilization System Post Market Clinical Follow-up Plan is the ongoing IlluminOss® Device Global Registry - A Prospective, Post-Market, Multi-Center Evaluation of the Clinical Outcomes of the IlluminOss Device; Protocol Number: REP-2012. The primary objective of the study is to collect safety and performance data on the IlluminOss Device when used to provide stabilization and alignment for the treatment of traumatic or impending and pathologic fractures.



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The study was initiated in 2021 with interim data available. As of 24 March 2025, fifteen (15) sites are currently participating in the registry including the lead site in Germany. Fourteen (14) sites have registered a patient, and a total of 300 patients have been registered in the database who met inclusion and exclusion criteria. One hundred and fifteen (115) patients were included in the interim analysis, having both baseline and latest follow-up VAS pain score values. The average follow-up was 299 days (mean, range, 299.35, 12-882 days).

Patient reports of pain as measured by VAS score showed improvement at early follow-up. Pain scores decreased at last follow up when compared with baseline (mean \pm SD), 1.96 ± 2.7 vs. 4.93 ± 3.15 , $p < 0.0001$). A total of 14 adverse events were recorded in 14 patients (12% overall complication rate). Eight of the 14 events (7% device or procedure related complication rate) were determined by the treating physician to be possibly or probably related to the device and/or procedure and the other 6 were determined to not be related to the device and/or procedure. The possibly related events included 2 cases of post operative infection, including wound complications; 2 cases of fracture nonunion; 2 cases of pain and/or loss of function; 1 case of inadequate fixation, and 1 case of progressive bone loss and increased implant stress resulting in implant failure. The unrelated events included 2 cases of fracture nonunion; 1 case of asymptomatic DRUJ instability about the device implant; 1 case of post operative wound healing disturbance; 1 case of secondary fall resulting in callus disruption; and 1 case of delayed healing due to patient non-compliance with post-operative instructions.

6. Possible diagnostic or Therapeutic Alternatives

Treatment options for long bone fractures depend on the characteristics of the fracture (e.g., articular involvement, fracture location, and degree of comminution), the type of bone, and the patient (e.g., age, general health, functional demands and expectations, bone quality and overlying soft-tissue quality). The degree of load-bearing exerted on the bone also factors into the fracture treatment algorithm.

The variety of treatment options available reflects the fact that no particular mode can be universally applied to the diverse fracture patterns across several anatomical regions. All bone fractures must be assessed for non-surgical versus surgical treatment.

Non-Surgical Treatment / Conservative Care

Non-surgical treatment of fractures may include: cast immobilization, a functional cast or brace, bed rest, or traction. Typically, non-surgical treatment consists of three phases: immobilization, passive/assisted range of motion, and progressive resistance exercises.

Surgical Treatment

For fracture cases where there is a high risk of unsatisfactory results such as loss of reduction, non-union, and impaired function, surgical treatment is often indicated in order to achieve stable reduction and fixation of the fracture.

There are several surgical treatment options available to achieve fracture reduction and fixation, including external fixation, plate osteosynthesis, intramedullary osteosynthesis, and intramedullary fixation with cement.



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External Fixation

A surgical option for fractures is external fixation, involving the insertion of multiple pins or wires on either side of the fracture site, which is connected to rods in a frame external to the skin. The approach is typically associated with open fractures due to less soft tissue disruption in comparison to open reduction with internal fixation. External fixation is also commonly used with corrective osteotomies (cutting of the bone) to stabilize the broken bone.

Internal Fixation with Plates / Screws

Plate fixation is indicated in situations where anatomic reduction and stabilization cannot be maintained with simpler, less invasive techniques. These include fractures with segmental bone loss, and open fractures where early range of motion is desirable due to a substantial amount of swelling and soft tissue trauma.

Intramedullary Fixation

Intramedullary fixation via nailing or wiring is associated with early patient mobilization, high rates of fracture union and low rates of intraoperative complications relative to other modalities of fixation. Currently, intramedullary reduction and fixation is considered the standard of care treatment for most long bone fractures utilizing an intramedullary nail with holes for stabilizing screws. The basic principle of intramedullary fixation is “dynamic osteosynthesis”, which is achieved by inserting a nail or similar implant into the medullary canal, which provokes reverse pressure and establishes elastic binding between the nail and bone.

Plate / Nail Combination Fixation

Plate fixation used in combination with intramedullary nailing can achieve and maintain fracture reduction. When used in combination, plates and IM nails can provide more stability and earlier mobility functions as stress forces are distributed evenly between bone and implant. This is of particular importance to elderly populations to help restore baseline function.

Cement Augmentation with or without Fixation

Percutaneous bone cement alone or in conjunction with metallic fixtures has been used for pain management and providing stability to various anatomical locations, most often in the spine and metastatic bone lesions. One issue that arises in osteoporotic bone lesions is the anchorage of the implants as osteoporosis causes bone mass to reduce. In such cases, PMMA or tricalcium phosphate bone cement can be used to increase the holding power of the implant.

7. Suggested Profile and Training for Users

The intended users of the IlluminOss Photodynamic Bone Stabilization System are Orthopedic Surgeons. The users are therefore medically trained healthcare professionals and are qualified in handling medical devices for their patients.

If the intended user requires more information that goes beyond the IFU, trainings adapted to the product, individual trainings can be booked online via homepage (www.iillumino.com); however, these trainings are not mandatory.



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8. References to any harmonized Standards and Common Specifications Applied

Technical Standards and Common Specifications.	Applied In Full or In Part
Compliance to a standard is considered to be full where the manufacturer has complied to the clauses within that standard that are applicable to the device. Partial compliance indicates that something within the standard could apply to the device and IlluminOss has determined not to apply that clause, with justification.	
BS EN ISO 13485:2016+A1:2021 Medical Devices Quality Management Systems Requirements for regulatory purposes	Full
BS EN ISO 14971:2019 Medical Devices Application or Risk Management to Medical Devices	Full
BS EN ISO 14602:2011 Non-active surgical implants — Implants for Osteosynthesis	Full
BS EN ISO 14630:2012 Non-active surgical implants - General requirements	Full
ASTM F1264-16e1 Standard Specification and Test Methods for Intramedullary Fixation Device	Full
ASTM F2052-21 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Full
ASTM F2119-07(2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	Full
ASTM F2182-19e2 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	Full
ASTM F2213-17 Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment	Full
ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment	Full
ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F1140 / F1140M-13(2020)e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	Full
ASTM D3078-02(2021)e1 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Full
ASTM F3039-15 Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	Full
ASTM F1886/F1886M-16 - Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Full
ASTM F1980-20 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	Full
ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials	Full
ANSI/AAMI ST72:2019 Bacterial endotoxins-Test methods, routine monitoring, and alternatives to batch testing	Full
BS EN ISO 15223-1:2021 Symbols to be used on Labels - Medical Devices	Full
BS EN ISO 20417:2021 Medical Devices - Info to be supplied by the manufacturer	Full
BS EN ISO 11135:2014+A1:2019 Medical devices -Validation and routine control of ethylene oxide sterilization	Full
BS EN ISO 13408-1:2024 Aseptic processes of health care products	Full
BS EN ISO 13408-2:2018 Aseptic processing of health care products – Part 2: Sterilizing filtration	Full
BS EN ISO 11607-1:2020 Packaging for terminally sterilized devices, Part 1: Requirements for materials, sterile barrier systems and packaging systems	Full
BS EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	Full
BS EN ISO 14644-1:2015 Clean rooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration	Full
BS EN ISO 14644-2:2015 Clean rooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
BS EN ISO 14644-3:2019 Clean rooms and associated controlled environments - Part 3: Test methods	Full
BS EN 17141:2020 Cleanrooms and associated controlled environments. Biocontamination control	Full
BS EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	Full
BS EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
BS EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	Full
BS EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Full
BS EN ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	Full
BS EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	Full
BS EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Full
BS EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Full
BS EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	Full



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Technical Standards and Common Specifications.	Applied In Full or In Part
Compliance to a standard is considered to be full where the manufacturer has complied to the clauses within that standard that are applicable to the device. Partial compliance indicates that something within the standard could apply to the device and IlluminOss has determined not to apply that clause, with justification.	
BS EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	Full
BS EN 62366-1:2015+A1:2020 Application of usability engineering for medical devices	Full
BE EN 60601-1:2006+A2:2021 (which is the same as IEC 60601-1 Ed. 3.2 en:2020) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Full
"BS EN 60601-1-2:2015+A1:2021 (a.k.a. IEC 60601-1-2 Ed. 4.1 en:2020)" Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Full
"BS EN 60601-2-18:2015 (a.k.a. IEC 60601-2-18 Ed. 3.0 b:2009)" Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	Full
BS EN 60601-1-8:2007+A2:2021 Medical electrical equipment Part 1-8-General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	Full
IEC 60825-9 Ed. 1.0 en:1999 Safety of laser products – Part 9: Compilation of maximum permissible exposure to incoherent optical radiation	Full
BS EN 55011:2016+A2021 Class A Industrial, Scientific and Medical Equipment – Radio-Frequency Disturbance Characteristics – Limits and methods of measurement	Full
CISPR 32 Ed. 2.1 b:2019 Electromagnetic compatibility of multimedia equipment - Emission requirements	Full
ISTA Test 3A General Simulation Performance Tests - Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less	Full
BS PD IEC/TR 60878:2015 Graphical symbols for electrical equipment in Medical Practice	Full
BS EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices	Full
BS ISO 17664-2:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices	Full
AAMI ST 79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities	Full
ASTM D6653M-13 Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method	Full
ASTM F2252M-13(2018) Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	Full
BS EN ISO 17737-1:2018+A1 2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	Full
BS EN ISO 16061:2021 Instruments for use in association with non-active surgical implants. General requirements	Full
AAMI TR12:2020 Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers	Full
"BS EN ISO 11137-1:2015+A2:2019 [BS equivalent of EN ISO 11137-1:2015+A2:2019, identical to ISO 11137-1:2006]" Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Full
"BS EN ISO 11137-2:2015+A1 2023 [BS equivalent of EN ISO 11137-2:2015, identical to ISO 11137-2:2013, and to ANSI/AAMI/ISO 11137-2:2013/(R) 2019]" Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	Full
MEDDEV 2.4/1 Rev 9 Classification of medical devices	Full
MEDDEV 2.12-1 Rev 8 Guidelines on a Medical Devices Vigilance System	Full
MEDDEV 2.12/2 Rev 2, Guidelines on Post-Market Clinical Follow-Up Studies	Full
BS EN ISO 14155:2020, Clinical Investigation of Medical Devices for Human Subjects, Good Clinical Practice	Full



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9. Revision History

Revision	Date Effective	Description of Change	Revision validated by Notified Body
A	11 November 2022	Initial Release for EU MDR 2017/745 CE Certification.	<input checked="" type="checkbox"/> Yes Validation Language: English <input type="checkbox"/> No
B	31 March 2025	Revision to support the EU MDR certification submission for the subject devices, to Notified Body BSI. All sections updated to align across technical documentation. Data sources updated include SOA literature search, subject device literature search, PMS data, and PMCF data.	<input type="checkbox"/> Yes Validation Language: English <input checked="" type="checkbox"/> No
A.5	16APR2025	Revision to consolidate the Basic UDI-DI into Section 1. Device Identification and General Information tables in Part 1 and Part 2.	<input type="checkbox"/> Yes Validation Language: English <input checked="" type="checkbox"/> No
A.6	17APR2025	Updated the revision to align with the MDR draft revision scheme.	<input type="checkbox"/> Yes Validation Language: English <input checked="" type="checkbox"/> No
A.7	29APR2025	Updates to align BUDI to DOC D.8 and TF-1001 P.8	<input type="checkbox"/> Yes Validation Language: English <input checked="" type="checkbox"/> No
A.8	01MAY2025	SSCP document validated by BSI	<input checked="" type="checkbox"/> Yes Validation Language: English <input type="checkbox"/> No



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PART B: SUMMARY OF SAFETY AND CLINICAL PERFORMANCE – PATIENT SECTION

Document revision: A.8
Date issued: 01 May 2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device Identification and General Information

Device Identification and General Information	
Device Trade Name	IlluminOss Photodynamic Bone Stabilization System
Manufacturer’s Name and Address	IlluminOss Medical, Inc. 993 Waterman Ave East Providence, RI 02914 USA
Basic UDI-DI	Photodynamic Polymer: M986MONOMERPH Photodynamic Bone Stabilization System Mini Sidefire (4x30mm - 8x80mm): ++M986MSSTRAIGHT6V Photodynamic Bone Stabilization System Sidefire Latitude (7mm x 160mm – 17mm x 280mm): ++M986SLSTRAIGHT7A Photodynamic Bone Stabilization System Sidefire Latitude (22/13mm x 160mm - 18/22mm x 90mm): ++M986SLTAPERDE9 Photodynamic Bone Stabilization System Mini-Sidefire Latitude (6mm x 40mm - 9mm x 160mm): ++M986MLSTRAIGHTZR Photodynamic Bone Stabilization System Mini-Sidefire Latitude (13/10mm x 70mm - 13/10mm x 120mm): ++M986MLTAPERED9X
Date of Initial CE Mark	2009

2. Intended Use of the Device

The IlluminOss System is a medical device used to help hold broken bones together so they can heal. It is approved for use in the European Union and can be used on bone such as collar bone, arm, hand, smaller bone in the lower



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leg (fibula), pelvis and foot. It can also help stabilize bones damaged by diseases like cancer. In the bigger leg bones (tibia and femur), it must be used with another device chosen by the doctor.

Intended Use	
Intended Purpose	The intended purpose of the IlluminOss System is to provide support to the bone so that it can heal.
Intended Users	Surgeons who operate on broken bones
Intended Patient Population	People whose bones have stopped growing with broken bones of the upper arm (broken upper arm for people over fifty), forearm, collar bone, small bone in the lower leg, hands and feet, , weak bone fractures of the ring of the pelvis, bone damaged by diseases such as cancer in the pelvis, and/or fractures of the upper and lower leg bones that carry a lot of weight used with another device chosen by the doctor to fix the bone.
Indications	<p>The IlluminOss System is indicated for use in people whose bones have stopped growing with broken bones of the upper arm (broken upper arm for people over fifty), forearm, collar bone, small bone in the lower leg (fibula), hands and feet. The IlluminOss System may be used to fix bones in the ring of the pelvis and to support parts of the pelvis that are damaged by diseases like cancer.</p> <p>The IlluminOss System may be used by itself or with other devices that the doctor chooses.</p> <p>The IlluminOss System may be used in the upper and lower leg bones that carry a lot of body weight only with another device chosen by the doctor to fix the broken bone.</p>
Contraindications	<p>Contraindications</p> <p><u>For all bones:</u></p> <ul style="list-style-type: none"> • Children whose bones are still growing. • People with Infections near the broken bone • Patients allergic to any of the parts of the device or dental glue. • Patients whose bones are too small for the device. • Difficult patients or patients with neurologic problems, not able to follow directions. • Infections that may spread to the bone that is broken. • Patients with poor blood flow • Broken bones that may have small pieces or break through the skin • Broken bones that are in so many pieces that the device can't go in the canal.

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Intended Use	
	<p><u>For upper arm fractures caused by trauma:</u></p> <ul style="list-style-type: none"> • Patients who are under 50 <p><u>For all bones excluding broken bones caused by diseases like cancer:</u></p> <ul style="list-style-type: none"> • Sickness that will stop the bone from healing. • Softening of the bone. <p>Patients with poor blood flow, weak muscles, or nerve problems.</p>

3. Device Description

What is the device and how does it work?	<p>The IlluminOss System works by a doctor making a small cut in the skin and a small opening in the bone. A thin plastic balloon goes inside the bone. A special liquid (light activated material) is pushed into the balloon to fill it and take the shape of the space inside your bone. A blue light is used to harden the liquid making the balloon solid. The solid implant holds the bone in place while it heals. The doctor stitches the small cut closed.</p> <p style="text-align: center;">Image of IlluminOss System in the Bone</p> 
What is the device made of?	<p>The balloon is made up of thin plastic balloon that can expand when the liquid is placed inside. The plastic has ink on it so the doctor can see the balloon on an x-ray.</p> <p>The liquid is a cement-like material that hardens when exposed to blue light. This is similar to what dentists use for fillings.</p> <p>The materials have been tested to make sure the devices are safe to place in the human body. There are no parts that contain medicines or that come from other humans or animals.</p>
Description of any other devices and products which are intended to be used in combination with the device	<p>The IlluminOss device uses a liquid material. Blue light turns the liquid into a solid. When the blue light is turned on, the liquid hardens inside the bone.</p> <p>To start the hardening, the IlluminOss device is used with the Photodynamic Light Curing System which includes a certain color blue light, a tube connection from the light to the device, foot pedal to turn the light on, power cord, and a clamp to hold the tube. The blue light is necessary for hardening the liquid inside the balloon; therefore, there are no other options that may be used.</p>



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	<p>The use of surgical tools in surgery is typically not optional. While the IlluminOss surgical tools are designed to only be used with the implant system, other surgical tools, such as wires, can be used. The surgeon picks the tools based on which bone is broken and how big the bone is. The blue light source and surgical tools are an important part of the surgery, including getting the device ready and putting it in the bone.</p> <p>There are many tools that can be used over and over to help the doctor with putting in or taking out the device. The tools include cutting tools to make an opening in the bone, drill bits, T-handles, guide wires, cutting tools to clean out the inside of the bone, flexible stabilizer and stabilizer tubes, tubes that allows for the liquid to go into the balloon, tools to separate the hardened liquid in the balloon from the tube, hooks, and slap hammers. These types of tools are often used to fix bone.</p> <p>Because the IlluminOss device is put in through a very small cut in the skin, it also includes tools that are only used once during the surgery and then thrown away. These tools include cannulas, introducer sheaths, dilators, air evacuation and monomer delivery syringes, and balloon delivery catheters. While these tools may not normally be used in other types of surgeries to fix bones, they have been used in other surgeries for many years.</p>
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4. Risks and Warnings

Contact your healthcare professional if you believe that you are having an issue related to the device or its use or if you are concerned about risks. This document is not intended to replace talking with your healthcare professional if needed.

How potential risks have been controlled?	A risk analysis has been done. The risk analysis shows that the risks of using the device have been reduced as low as possible. The ways the risks have been reduced include testing the device, published patient data on the product use, and product labeling and use instructions.
What are the risks and side effects?	<p>Risks associated with the use of the IlluminOss System and similar devices placed in the canal of the bone are:</p> <ul style="list-style-type: none"> • The device may fail (loosen, break or bend) when the bone does not heal like it should • The bone may not heal properly • Reaction to the materials or surgery • Infection • Blood clot or tissue damage • Broken bone around the device

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- Damage to the tissues around the device or surgery site
- Pain or loss of your ability to do activities of daily living
- Another surgery in the same location
- Doctor is unable to correctly place the device in the body or remove the device if needed
- Electrical issues from the light source
- Issues from heat during hardening
- Liquid leaking before it hardens

The risks were looked at when the device was used as intended. Unless noted, these events are considered events related to the device.

Event	Clinical Study (n=403 patients)	Journal Article (n=>2,500 patients)	Post Market Surveillance (>9,000 devices)
Bone not healed correctly	0.0-1.7%	0.5%	0.2%
Another surgery in the same location	0.0-6.8%*	2.2-2.9%	NR
Device Failure	0.0-11.1%*	3.3%	0.01 - 0.3%
Bone healing takes longer	2.3%	0.7%	0.6%
Pain	1.7 - 3.7%	1.8%	NR
Infection	1.7%	1.5%	0.02%
Damage to the tissues around the device or surgery site	1.7%	2.7%	NR
Balloon Damage	NR	NR	0.22%
Heart attack or other heart related event	NR	NR	NR
Blood clot	NR	6.3% (5 events)	NR
Liquid does not fully harden	NR	0.5% (2 events)	0.11%
Screws become loose	4.6%	1.7% (1 event)	NR
Device not properly attached/ Loses its hold	0.9%	NR	0.03%
Packaging Damage	NR	NR	0.03%

NR=Not Reported

*Higher events were related to the use of the device in the pathological population.

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	Other event types were reported in low numbers in small studies. None were unexpected given the kinds of patients who receive this treatment, procedure-type, or device-type. Post market surveillance data captures events during surgery or after surgery that happened more than once.
What warnings and precautions should a patient know?	A list of warnings and precautions is given to the doctor to make sure the doctor has all the information needed to properly put the device in the body. Follow-up visits with your doctor after surgery are recommended for all patients.
Warnings and precautions	<p>Warnings</p> <ul style="list-style-type: none"> ⚠ Do not reuse parts of the system that are meant to be used only once and then thrown out, doing so may result in injury or death. ⚠ Throw out and do not use opened or broken packages. ⚠ Do not use any parts after the expiration date. ⚠ Pick the right size. Before putting it in: <ul style="list-style-type: none"> ⚠ Make sure the device is long enough to go across the broken bone and is not longer than the bone. ⚠ Make sure that the device diameter is large enough to so that it touches the inside of the bone. ⚠ Make sure that the tool that is used to cut the tube attached to the balloon can reach the balloon. ⚠ The hardening heats up the device for a short time. ⚠ Do not touch the balloon with anything sharp until the liquid hardens. ⚠ Do not fill the balloon with anything other than the liquid provided using the tools in the system. The balloon is made of a plastic that does not stretch. ⚠ Do not add anything to the liquid. ⚠ Do not use any other light on the liquid other than the IlluminOss System light, block the liquid from light after it is taken out of the bottle. ⚠ Do not bend or kink the light fiber, tubes or balloon device. Handle the system with care. Large bends or kinks in the system will stop the blue light from getting to the liquid and the liquid will not harden all of the way. ⚠ If an X-ray shows that the device is not touching the inside of the bone, the device should be taken out, the bone measured again, and a new device that is big enough to touch the inside of the bone should be used the user. ⚠ Do not turn on the blue light until the balloon is in the right position and the broken bone is put back together. Turning on the blue light will harden the liquid, and this cannot be undone. ⚠ The liquid in the balloon must be exposed to blue light for a specific amount of time in order to fully harden the device. A partially hardened device cannot be used to finish the surgery. If it thought that the liquid might not be hardened, it should be exposed to the blue light for another time cycle.



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	<p>⚠ Not putting the fracture back together or unanticipated events after surgery may affect the bone between the bone and hardened device which may lead to the device moving. Patients should see their doctors and get X-rays from time to time to make sure that the device is not moving.</p> <p>⚠ Deep wound infection is a serious problem that can occur after surgery and may require hardened device to be taken out. Deep wound infection may not be seen until several years after surgery.</p> <p>Precautions</p> <ul style="list-style-type: none"> • Read instructions before using. • Before using the IlluminOss System, surgeons should be very familiar with what the system is made of, how it works and how to use it. • Follow good surgical principles and technique during the use of the IlluminOss System. • The liquid may cause a reaction when it touches skin. In case of contact with skin, wash right away with soap and water. • The IlluminOss System may only be used in the large bones of the leg with another device picked by the doctor to fix the bone. In these leg bones, the IlluminOss system may not be used by itself.
Has the product ever been recalled?	There have been no device recalls.

5. Summary of Clinical Evaluation and Post Market Clinical Follow-Up

5.1 Clinical Background

The IlluminOss System helps bones heal with a small surgery. It has been used since 2009 and has been shown to be safe and effective. While there are some risks, they are low compared to the benefits of healing and pain relief. If you have any concerns, talk to your doctor.

5.2 Clinical Evidence for CE Marking

CE marking was based on data collected from four clinical studies and published patient data that studied the safety and performance of the IlluminOss System. A summary of the clinical studies is below:

Table 4: IlluminOss System Clinical Study Information

Study Description	Study of the device in fixing broken bones in the upper arm in Europe	Study of the device in fixing broken bones in all bones in Europe	Study of the device in fixing damaged bone from cancer in the upper arm in the United States	Study of the device in fixing damaged bone from cancer in the upper arm in the Europe
Device Used	IlluminOss System	IlluminOss System	IlluminOss System	IlluminOss System

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What was the purpose of this Study?	To collect safety and performance data on the use of the IlluminOss System in fixing broken bones in the upper arm	To collect safety and performance data on the use of the IlluminOss System in fixing broken bones in all bones	To collect safety and performance data on the use of the IlluminOss System fixing damaged bone from cancer in the upper arm	To collect safety and performance data on the use of the IlluminOss System in fixing damaged bone from cancer in the upper arm
How long were patients studied for?	Patients were studied at 6 months and 1 year after surgery	Patients were studied from the time of surgery and up to 2 years after surgery	Patients were studied at 7-days, 30-days, 90-days, 6 months and 1 year after surgery	Patients were studied at 7-days, 30-days, 90-days, 6 months and 1 year after surgery
Where did the study take place?	The Netherlands and Germany	Europe	US	Austria, Germany, and the Netherlands
Who participated in the study?	44 patients	132 patients with 149 fractures	81 patients	14 patients
What anatomical location was treated?	Upper arm	Upper and lower arm, hand, pelvis, and leg	Upper arm	Upper arm
When did the study take place?	2015 - 2017	2010 - 2014	2015 - 2016	2015 - 2016
How did the device perform?	Bone healing was shown in 96% of patients at 1 year after surgery. Improvement in pain and disability was shown after surgery.	The doctor was able to successfully place the device in 100% of cases Range of motion was within normal limits in 87% of patients at 3 months follow-up Healing results were excellent with 1 year of follow up.	Patients saw improvement in pain and function.	Patients saw improvement in pain and function.
What were the side effects related to the device?	5 (11.4%) complications were reported as possibly related to the device including: 1 dislocation of bone, 1 delayed fracture union and device breakage, and 2 screw dislocations	No complications were considered related to the use of the device, although 2 events resulted in the device breaking	12 device-related complications in 6 patients included: 2.5% severe device breakage, 8.6% moderate device breakage, 3.7% medical device site pain (moderate)	No device related complications



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			Only 5 patients (6.2%) required secondary surgery.	
Were there any unexpected or serious side effects?	There were no unexpected or serious side effects	There were no unexpected or serious side effects	There were no unexpected or serious side effects	There were no unexpected or serious side effects
Conclusion of data	IlluminOss System is safe and effective for the treatment of upper arm fractures adults.	Positive safety and healing parameters were seen for the IlluminOss System.	The data from the study did not show any unexpected events for the patient population.	The data from the study did not show any unexpected events for the patient population.

Journal articles (through December 2024) included 72 studies with over 2,480 patients treated with the IlluminOss System. The studies show the device is effective and safe.

The device fixes bones which helps with bone healing. Other benefits include patients saying that they are healed, feeling less pain and moving better. Also, the studies show that the device is safe when used in as it is supposed to be. A small number of problems were reported in the data.

In conclusion, clinical data from the studies and journal articles show the device does fix bone and is safe when used as it is supposed to be.

5.3 Safety

The studies that were done to get the product approved for use and journal articles have shown that the device is safe with few patient's bones not healing, needing another surgery, or the device breaking. All risks seen in the patient studies and published patient data were expected with no unexpected or serious problems. The IlluminOss System has been used in surgery since 2009 with an overall complaint rate of 1.25%. In conclusion, the clinical data of the IlluminOss System shows the benefits are greater than the risks.

IlluminOss continuously watches and collects safety data on the IlluminOss System. IlluminOss monitors the safety of the device by reviewing public databases, complaints from customers and patients, safety and performance surveys, and information reported in published patient studies. In addition, IlluminOss has a study that is ongoing to collect more data on the device to make sure that it is helping patients in the way it is supposed to. This study started in 2021 and has 300 patients planned to join the study covering all uses of the device. So far, 115 patients have had pain levels checked out to 299 days after being treated with the IlluminOss System. The initial results show pain levels improved over time. There have been 8 side effects possibly related to the device including 2 infections, 2 bones not healed correctly, 2 cases of pain, 1 device not properly attached, and 1 device failure. There have been no unexpected or serious side effects. The study continues to show that the IlluminOss System is safe and effective.

6. Possible Treatment Options

When considering other treatments, it is recommended to talk to your healthcare professional who can take a look at what is right for you.



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Treatment options for broken or damaged bones depends on the type of bone, the type of break or damage to the bone, and your health.

The treatment options are because no one option can fit all types of broken or damaged bone. Each patient must be looked at by their doctor to see which treatment is best. Treatment options may include:

Non-Surgical Treatment

Non-surgical treatment may be a cast or brace, bed rest, or traction (using pulling forces to hold your bone in place). Usually, non-surgical treatment consists of several phases: stop the bone/s from moving followed by slowly increasing range of motion and exercise.

Surgical Treatment

For cases where there is a high risk of the bone not healing in the right way, the doctor may choose surgical treatment. These include external fixation, fixation with plates and screws, or fixation with a rod. In some cases, cement may be used to fill the damaged bone.

External Fixation

External fixation uses multiple pins or wires put in through the skin and into the bone on both sides of the broken bone. The pins are then connected to rods that make a frame outside of the skin to hold the bone together while it heals.

Fixation with Plates and Screws

Plate and screw fixation involves a metal plate and/or screws placed across the broken or weak bone to hold the bone together while it heals.

Fixation with a Rod

Fixation with a rod uses a metal rod (or nail or pin) that is placed inside the space in the center of the bone. The rods include holes for placing screws through it to hold the rod in place. The screws are placed through the skin, into bone and through the rod to hold the rod in place. Rod fixation holds the bone together while it heals.

Fixation with a Combination of Devices

Plate fixation and rod fixation can be used together to help with bone healing. When used together, plates and rods can better prevent movement of the bone. This is more important in people with weak bone to help them function.

Cement with or without Fixation

Cement can be placed to help hold the bone in place while it heals, most often in the weak (osteoporotic) bone, the spine, and damaged bone from cancer.