



CORELINK FLXfit® & FLXfit®15 LUMBAR CAGE SYSTEM

IMPORTANT NOTE: The user of this system must read and acknowledge the conditions of this insert prior to use

Consult the product electronic instructions for use for all current languages and latest document revision at corelinksurgical.com/ifu or by scanning the barcode on the product labeling.

PHYSICIAN NOTE

The physician must convey the important medical information in this document to the patient.

DESCRIPTION

FLXfit & FLXfit15 are expandable, articulating TLIF interbody fusion devices (IBFD), both used in conjunction with supplemental fixation to provide structural stability in skeletally mature individuals following total or partial discectomy. The FLXfit & FLXfit15 are available in a range of sizes with height expansion which accommodates lordotic curve up to 15°. A bullet-nose design facilitates self-distraction and ease of insertion and teeth on the inferior and superior surfaces of the devices assist in stabilization of the construct. The open architecture of the devices allows them to be packed with autogenous bone graft material, i.e. autograft.

Implants in the FLXfit Lumbar Cage System are manufactured from the following materials:

- Medical grade Titanium Alloy (Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)) Alloy for Surgical Implant Applications (UNS R56401).

INDICATIONS FOR USE:

The FLXfit & FLXfit15 Intervertebral body fusion devices are indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. The FLXfit & FLXfit15 devices are intended to be used with supplemental spinal fixation system and with autogenous bone graft.

CONTRAINDICATIONS:

This device is not intended for cervical spine use.

Contraindications for use of FLXfit and FLXfit15 include, but are not limited to:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
8. Suspected or documented allergy or intolerance to implant's materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or Pseudarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Hemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).

16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

Note: This list may not include all of complications cause by the surgical procedure itself.

Additional surgery may be required to correct these potential adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS:

PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances could compromise the result. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical technique, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke will have reduced incidence of bone fusion. These patients must be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by CoreLink. It is therefore mandated that CoreLink implants are not used with instruments from any other source.

Never, under any circumstances, reuse a FLXfit or FLXfit15 implant. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

The CoreLink FLXfit & FLXfit15 Cage System has not been evaluated for safety and compatibility in the MR environment. The CoreLink FLXfit & FLXfit15 Cage System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CoreLink FLXfit & FLXfit15 Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications must be selected.
2. Patient conditions and/or predispositions such as those addressed in the contraindications must be avoided.
3. Care must be taken in the handling and storage of the device(s). They must not be scratched or damaged. Devices must be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon must be familiar with the various devices before use and must personally verify that all devices are present before the surgery begins.
6. The size of device for the case must be determined prior to the beginning of the surgery. An adequate inventory of implant sizes must be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual instruments may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.
8. Prior to use, instruments must be inspected for signs of wear, damage and proper function. If you suspect an instrument is damaged, please contact CoreLink for a replacement.
9. Follow the Cleaning and Sterilization procedures below.

CLEANING AND STERILIZATION

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments must not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments).

Manual Cleaning Instructions:

1. Completely submerge the instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to

gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution must be changed on a regular basis in order to ensure its effectiveness.

- Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
- Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices.
- Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
- Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
- Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
- Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

NOTE: Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

Automated Cleaning Instructions:

- Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
- Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection.

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	2-minute prewash with cold tap water
2	1-minute enzyme spray with hot tap water
3	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
4	15-second hot tap water rinse
5	2-minute thermal rinse (80-93°C/176-200°F)
6	10-second purified water rinse (64-66°C/146-150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:

- The washer manufacturer's instructions must be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the implant surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions

Implants and instruments of the CoreLink FLXfit & FLXfit15 Lumbar Cage System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, testing has shown that effective sterilization may be achieved as follows:

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

Instruments and implants must be sterilized in the steam sterilization cases provided by CoreLink. Instrument and implant sets must be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used.

REUSABLE RIGID STERILIZATION CONTAINERS

The FLXfit & FLXfit15 Lumbar Cage System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JK440, JK442, JK444, JK446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10⁻⁶ sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions

for Use of the Manufacturer (<https://www.aesculapusa.com/products/instructions-for-use>).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the FLXfit & FLXfit15 Lumbar Cage System is not recommended.

IMPORTANT SYSTEM CONSIDERATIONS AND WARNINGS

- Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion of implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. However, the presence of dissimilar metals in contact accelerates corrosion. For instance, where titanium and stainless steel are in contact, the stainless steel is subject to corrosive attack. Corrosion may accelerate failure of implants through fatigue fracture. Corrosion also causes metal compounds to be released into the body. To minimize effects from corrosion, implant components that encounter other metal objects, must be made from like or compatible metals.
- Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain disc height restoration until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
- Implant Selection.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.
- Patient Considerations.** The following must be considered when evaluating whether a patient is a candidate for such a procedure:
 - Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
 - Lifestyle or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she must not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
 - Alcoholism, drug abuse, or mental conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
 - Degenerative diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
 - Implant sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
 - Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implants to become displaced or damaged and may cause the implant to migrate and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.
- Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.

- **Implant Removal.** Spinal implants of this type may require removal if the desired clinical and surgical outcomes are not obtained. The surgeon must carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon must provide postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. Although uncommon, permanent implantation of this device may result in the following: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury; and (7) Risk of additional injury from postoperative trauma.
- **Do Not Reuse Implants.** An implant previously implanted must never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

INTRAOPERATIVE

1. The instructions in any available FLXfit & FLXFit15 surgical technique guide must be carefully followed.
2. Verify the integrity of the sterile wraps or containers. Never use items where a sterile barrier is damaged. Prepare the surgical site for implant introductions.
3. At all times, extreme caution must be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
4. Breakage, slippage, or misuse of instruments or implants will cause injury to the patient or operative personnel.
5. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
6. Proper selection of the shape, size, and design of the implant by the surgeon and subsequent placement during surgery are extremely important. Refer to the *FLXfit™ Lumbar Cage System Cage System Surgical Technique Guide* for specific instructions related to the surgical procedure.
7. The surgeon must be thoroughly familiar not only with the medical aspects of the FLXfit & FLXFit15 but must also be aware and instruct the patient on the use and limitations of implants.

POSTOPERATIVE

Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
2. The patient must be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices must be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices must be treated in such a manner that reuse in another surgical procedure is not possible.

REVISION SURGERY AND IMPLANT REMOVAL

The implants of the FLXfit & FLXFit15 System are intended for permanent implantation and are not required to be removed. However, removal may be advisable in the following situations:

- Implant migration or breakage
- Non-union
- Pain due to the implant
- Infection

Implant removal must be performed using the supplied FLXfit & FLXFit15 System instruments. Implant removal must be performed by first securely attaching the system-specific removal instruments to the implants, then carefully removing them from the surgical site ensuring any surrounding anatomical structures are not damaged

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, must notify the distributor or CoreLink, LLC. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor/CoreLink, LLC must be notified immediately. If any CoreLink, LLC product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor/ CoreLink, LLC must be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

CAUTION: Under federal law, this device may only be sold by or on the order of physician.

LIMITED WARRANTY AND DISCLAIMER

CORELINK PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company.

For further information contact:



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Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Lot Number – Indicates the manufacture’s batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture’s catalogue number so that the medical device can be identified	5.1.6
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4