ENG50783 Rev12

UNITED U-Motion II Acetabular Components
Safety statement

EC REP

mdi Europa GmbH
Langenhagener Straße 71
30855 Langenhagen, Germany
TEL: +49-511-3908 9530
FAX: +49-511-3908 9539

United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-577-3351
FAX: +886-3-577-7156

CE 2797 STERILE R STERILE EO

85 % 30 % 35℃ 7℃ Rx only

Note: The CE mark is valid only if it is also printed on the product label.

DESCRIPTION

UNITED U-Motion II Acetabular components include acetabular shell, Delta ceramic and XPE cup liners, Ti cancellous screw and metallic screw-hole covers. It is used with the United U2 hip stems and the ceramic and metallic femoral heads. It is a modular type of product system with hemispherical design with HA/Ti plasma spray (HA cup, HA+ cup) or Ti plasma spray (PS cup, PS+ cup) on the metallic shell. Three types for different screw hole distributions are available: cluster-hole, no-hole, and multi-hole. Screw holes with spherical geometry are intended for variable screw fixation angle. Delta ceramic liner fit into the metallic shell by taper mechanism and XPE and E-XPE cup liners fit into the metallic shell by snap-in locking mechanism. XPE and E-XPE cup liner is capable of 12 scallops for angle adjustment. The Delta ceramic liner is a high-purity alumina ceramic compound in accordance with ISO 6474-2.

Note: The delta ceramic liners and HA+ cups are not for sale in the US.

MATERIALS

ASTM F620 Ti alloy (raw materials: ASTM F136/ISO 5832-3)
Acetabular cup, HA / Ti plasma spray or Ti plasma spray
ASTM F1580 Titanium
Metallic powder for plasma spray
ASTM F1185 Hydroxylapatite

Hydroxylapatite powder for plasma spray
ASTM F136 Ti alloy (raw materials ASTM F136/ISO 5832-3)
Ti cancellous screw, screw-hole covers
ISO 6474-2 Highly pure aluminum matrix with zirconia reinforcement
Ceramic acetabular cup liner--delta
ASTM F648/ISO 5834-1 and ISO 5834-2
extruded highly-cross linked UHMWPE bars XPE cup liner
ASTM F648/ASTM F2695/ISO 5834-1 and ISO 5834-2
Vitamin E-blended highly cross-linked UHMWPE E-XPE cup liner

INDICATIONS

The device is used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4. Correction of functional deformity.
5. Treatment of nonunion femoral neck and trochanteric fracture of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended for cementless use only.

CONTRAINDICATIONS

1. Any active or suspected latent infection in or about the hip joint.
2. Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
3. Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation to the prosthesis.
4. Skeletal immaturity.
5. Patients who is sensitive to any materials of the device.
6. The U-Motion II acetabular components are designed for uncemented application and single use only.
7. For cup positions which are not recommended, **Ceramic Liner** should not be used. For cup positions which inclination exceed or fall below a value of 40-45°, anteversion exceed or fall below a value of 10-20°, ceramic liner should not be used. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the femoral head from the ceramic liner. For cups in retroversion, no ceramic liners should be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the ceramic liner associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reactions, loosening of the prosthesis and in

extreme cases ceramic breakage. Ensure adequate joint tension is achieved on implantation, as dislocation can lead to the adverse results aforementioned listed.

POSSIBLE ADVERSE EFFECT

1. While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
2. Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
3. Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
4. Fatigue fracture of ceramic liner had been reported although in a small percentage of cases.
5. Acetabular cup fracture may occur in the heavy, physically active individual or when contralateral joint disability results in a disproportionate distribution of weight on the reconstructed joint.
6. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
7. Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; respiratory disorders, including emboli; myocardial infarction or death.
8. Acetabular pain may occur after acetabular replacement due to loosening of the implant or tissue inflammation.
9. Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock. Metal sensitivity reactions have been reported following joint replacement.
10. Adverse effects may necessitate re-operation, revision, arthrodesis of the involved joint, Girdle-stone and/or amputation of the limb.
11. With all implant devices; asymptomatic, localized progressive bone absorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal and/or ceramic. Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Also, particulate can be

generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.

WARNINGS

1. This device should only be applied by qualified and specially trained surgeons who have the corresponding knowledge and experience in the field of hip joint replacement. The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
2. Factors outside the control of United are not United's responsibility, including any modification after delivering to the hospitals and any mishandled pre-operation, intra-operation or post-operation. The operating surgeon shall be responsible for any negative effects and complications resulting from non-compliance with the user instructions, improper treatment of the material or an incorrect assessment of indications.
3. The U-Motion II acetabular components are designed for single use only. Never use prosthetic components which have been used before.
4. Surgeon must inform the patient about the relative information of this device, including its effects and the possible risks during operation, possible post-surgical complications, as well as inspect the materials biocompatibility of the products used with this device.
5. If the product does not meet the specifications, please immediately notify the supplier, and dilate the problems that occur. If possible, please return the product to the supplier.
6. Only unused implants taken from the original packaging may be used. Never reuse an implant again, even though it may appear undamaged. Reuse of this product will cause the risk of cross infection and unpredictable health threat. Likewise, a ceramic liner with any kind of damage must not be used, but discarded instead. This also applies to a ceramic liner that has fallen to the floor, for example. With ceramic liners that have already been used, there is risk that they could have damages invisible to the naked eye. Since any kind of damage can adversely affect the ceramic's functionality and/or stability, a safe use cannot be guaranteed. For this reason, only unused and undamaged ceramic liners packaged in their original packaging may be implanted.
7. Exclusively use brand-new components for the configuration of metal shells and inserts, as an exact fit of the insert in the shell must be guaranteed.
8. On rare occasions, in vivo fracturing of the ceramic liner may occur. In order to minimize this risk, the ceramic liner was individually examined before delivery. One cause of failure can be the incorrect fixation of the ceramic liner with the cup. The use of prosthesis components which are not released by United for combination with a ceramic liner can also lead to the fracture of the ceramic liner. The same applies if the recommended position of the ceramic liner (inclination/anteversion) is not observed.
9. The position of the prosthesis components has a direct influence on the range of movement and thus represents a potential risk of impingement, luxation or subluxation. For cup casings which are too steep, surface pressure on the acetabular edge increases. This can lead to

increased wear and tear. The cup position is oriented in accordance with the safety zone described by Lewinnek.

10. The joint may dislocate with strenuous exercise, or subluxate through the impingement of implant components or soft tissues.
11. The inclination of the cup components should not significantly exceed or fall below a value of 40-45°. The anteversion of the cup components should not significantly exceed or fall below a value of 10-20°. Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the ceramic femoral head from the ceramic liner. For a cup which lies outside the above-mentioned values, a ceramic liner must not be used. For cups in retroversion, no ceramic liners should be used.
12. Bearing areas must always be clean and free of debris prior to assembly.
13. Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**
14. United strongly advises against the use of another manufacturer's femoral component with any United acetabular cup component. This device may only be combined with prosthetic components released by United for use with this device. U-Motion II Acetabular cups can only collocate with Delta ceramic liners or XPE or E-XPE cup liners in this system. Only ever use Delta ceramic liners with United ceramic femoral heads. Coupling with a different femoral head or with a ceramic head from other manufacturers is not allowed. Any such use will negate the responsibility of United for the performance of the resulting mixed component implant.
15. Except general instruments, this device may only be implanted combined with United implants by using the instruments released by United. Any improperly use will negate the responsibility of United.
16. Ceramic head replacements (See Fig. 6):
    —In case a ceramic component breaks, a pairing of ceramic head with polyethylene liner or a pairing of ceramic head with ceramic liner must be used in a revision.
17. Remove screw hole cover from well-seated multi-hole cup might lead to cup unstable. We highly suggest that surgeon removes the screw hole cover before cup implantation if additional screw fixation is needed.
18. An obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

PRECAUTIONS

PREOPERATIVE

1. Surgeon must inform the patient that an artificial joint cannot be subjected to the same demands as a natural joint, and the patient should not have unrealistic functional expectations. Surgeons should instruct patients about the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient’s weight or activity, and be taught to govern their activities accordingly. Any kind of competitive sport, i.e. sport types with jolting or jerking movements, involving the artificial joint is contraindicated and leads to excessive strains. If the patient is involved in an occupation or

activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. An additional risk is posed by patients with high body weight, with a weak osseous system or by those who are physically very active. Brief, extreme overloading such as a trauma, an accident or excessive strain can lead to fracturing, sometimes long after the event. The patient also must be informed of possible post-surgical complications.

2. The implant must be carefully preserved and transported properly. Cut or scratch the surface of the implant will significantly reduce its static, fatigue strength or influence its friction characteristics. These may have small defects and internal stress patterns invisible to the naked eye which may lead to early failure of the device. Implants and instruments are not stored in the salt air.
3. Enough sizes of the implants should prepare for surgery, including larger and smaller size. Special size is also recommended to prepare.
4. Pay attention to special conditions of patient as the description of contraindication.
5. Preoperative screening should be considered if the materials of the device cause allergy or other reaction of patients although this condition occurs seldom.
6. Radiographic templates are available to assist in the preoperative prediction of component size and style.
7. Surgeon must read the surgical protocol carefully before operation.
8. Check the colored sterilization indicator of the packaging.
9. The labels, especially the size designation the package labels, must be checked to see that they match the labels on the devices.

INTRAOPERATIVE

1. The United Surgical Protocols provide additional procedural information.
2. Appropriate selection, placement and fixation of the femoral stem and/or Acetabular components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
3. If use bone screws with acetabular components, care must be taken not to damage blood vessels, nerves or peritoneal tissue when drilling screw holes and inserting screws. Use drill guide before drilling screw holes and measure the depth of drilling by the depth gauge for selecting the proper length of screw. Don’t use screws longer than 50 mm. Bone screws must be completely fixed into the screw hole of the acetabular shell, so that the acetabular liner can properly be embedded within the acetabular shell.
4. Before place the **Delta ceramic or XPE or E-XPE cup liner** into the cup, make sure that any foreign matter from the prosthesis components, such as tissue particles, bone or cement particles from the surface of the acetabulum cup has been removed.

5. The Delta ceramic or XPE cup liner should be placed and fitted in accordance with United's instructions (see the figures below).
6. At time of assembly, inner taper of the shell must be clean and dry to ensure proper seating and assembly security.
7. For ceramic liner insertion, fix the ceramic liner centrally in place in the metal shell with the greatest of care, following the diagrams below (Figs. 1~5) provided for this purpose. A perfect fit of the ceramic liner in the cup must ensue.
8. Before the final fitting of the Delta ceramic liner with a plastic impactor, the correct fit of the liner should be tested with the finger. Never bring a metal hammer into contact with the Delta ceramic liner.
9. For XPE and E-XPE cup liner insertion, ensure the tabs on the liner are aligned with the indentions in the shell. Impact firmly with the mallet until the liner is fully seated. The liner should sit flush with the face of the shell.
10. Care must be taken to protect the components from being marred, nicked or notched as a result of contacting with metal or abrasive objects.
11. Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
12. The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.

    —Before a decision is made to implant a Delta ceramic or XPE or E-XPE cup liner, a sample inlay made of plastic is placed into the cup and the stem components are implanted. Please take care that the plastic insert will be removed after checking.

    —The joint is tested for free movement and stability using sample heads of the intended diameter. Please take care that the plastic femoral head will be removed after checking.

    —The joint may not luxate with movement, or subluxate through the impingement of implant components or soft tissues.

POSTOPERATIVE

1. Postoperative care and instructions for patients are very important. Postoperative weight bearing must increase gradually and individually.
2. After postoperative, patients must be reminded, do not make large movement of hip joint individually with no help or without auxiliaries, especially when going to the toilet or performing the higher degree of activities.
3. Moving the patient carefully and paying attention to support the affected area and avoid exerting pressure on it.
4. The postoperative treatment should take care of the strength of muscles around the hip and increase activity gradually.
5. Regular X-rays shall be taken to evaluate if the implant move, loose, bend, fracture or the cement or bone loss. If these conditions occur, please pay attention to the progress of condition and consider the advantage of revision.

6. Should consider the use of antibiotics in patients to prevent bacterial infection.

PACKAGING AND LABELING

1. This device is sterile and double packaged to ensure the product is suitable for surgery at any time. The sealed package can protect the implants and keep the sterilized condition under normal storage and transport.
2. The packaging of all products should be inspected for their integrity and should only be accepted with proper packaging and labeling intactness.
3. All implants should be stored in their original packaging in a clean and dry environment.
4. If the sterile blister pack became wet or damaged, the implants should not be used and be returned to the supplier.

STERILIZATION

1. All implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label.
2. Ceramic and metal components are sterilized by gamma radiation at at least 25 kGy, while the plastic components are ethylene oxide sterilized. All components can be verified from the colored sterilization indicator on the packaging.
3. The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of any flaws, the product must be assumed nonsterile. Special trial prostheses are available to avoid having to open any aspect of the sterile package prior to component use.
4. This device delivered in sterilized form and must be kept unopened in the original packaging until it is ready to be used. Check the sterilization expiry date on the sterile packing and check the protective packing for damage prior to use. If the sterilization expiry date has passed or in case of any damage to the protective packaging, the implants must not be used or re-sterilized and must be discarded or returned to the supplier.
5. Aseptic methods must be followed when removing the component from its original packaging and during the entire implantation. In the event of contamination, this product must be discarded.
6. Ceramics sterilized by gamma rays may be changed in color. This has no influence on the strength or any other characteristic of the ceramic liners.
7. The implant should not be used if the outer sterile barrier is damaged or intentionally opened during surgical use but the implant was not used during surgery and was taken out of the sterile field.

RE-STERILIZATION

If the package is opened, but the product is not used, the component must not be resterilized (including Delta ceramic and XPE components) and must be returned to the supplier. A suitable handling will be done. HA / Ti plasma spray cup needs special clean procedures and ceramic components cool down quickly after sterilization with high temperature could affect their mechanical properties.

STORAGE AND HANDLING

1. All implants must be stored unopened in the original packaging in a clean and dry environment and be protected from sunlight and extremes in temperature.
2. The protective packaging must be inspected for signs of damage before the devices are removed, since this could affect the sterility. The sterility expiry date must be observed. If the protective packaging is damaged or the sterility date has passed, the implants must be returned to United. Protection may only be removed directly before use.
3. The implants which can no longer be used may be returned to the manufacturer for correct disposal.
4. Ceramic liners are extremely sensitive to damage. Even small scratches or impact points can cause wear, tear or fracture and lead to complications. Extremely careful handling is therefore required.

Interaction with drugs

There have been no reported interactions with drugs to date.

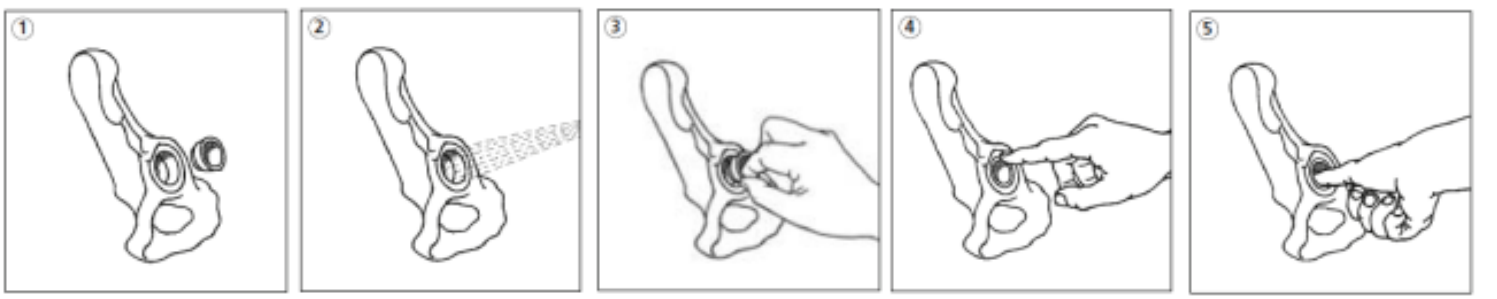


Fig. 1: After having inserted the cup casing in the acetabulum, make sure the position of the acetabular cup and its function, i.e. movement of the joint is thoroughly checked using a trial. It is important to make sure that the screws are completely countersunk.

Fig. 2: Remove the trial after having checked both the position of the cup and the function of the joint and be sure to rinse and dry the cup casing. Ensure that there aren't any bone or tissue residues left in the fixation area.

Fig. 3: Insert the **Ceramic Liner** by hand as described in the diagram: pick up the **Ceramic Liner** with two fingers and introduce it into the cup casing. The **Ceramic Liner** will slide into the casing automatically as soon as the fingertips contact the rim of the cup casing.

Fig. 4: Check whether the **Ceramic Liner** has been positioned correctly by feeling the rim of the cup with your fingers, and correct, if necessary. The rims of the metal shell and of the ceramic liner must be flush and on the same plane.

Fig. 5: If the **Ceramic Liner** is positioned correctly, fix in position by pushing it in with your thumb. For the final fitting of the **Ceramic Liner**, an impactor suitable for **Ceramic Liner** and recommended by the prosthesis company is used to firmly position it with a slight hammer stroke in the axial direction.

ATTENTION! Never bring a metal hammer into contact with the ceramic liner!

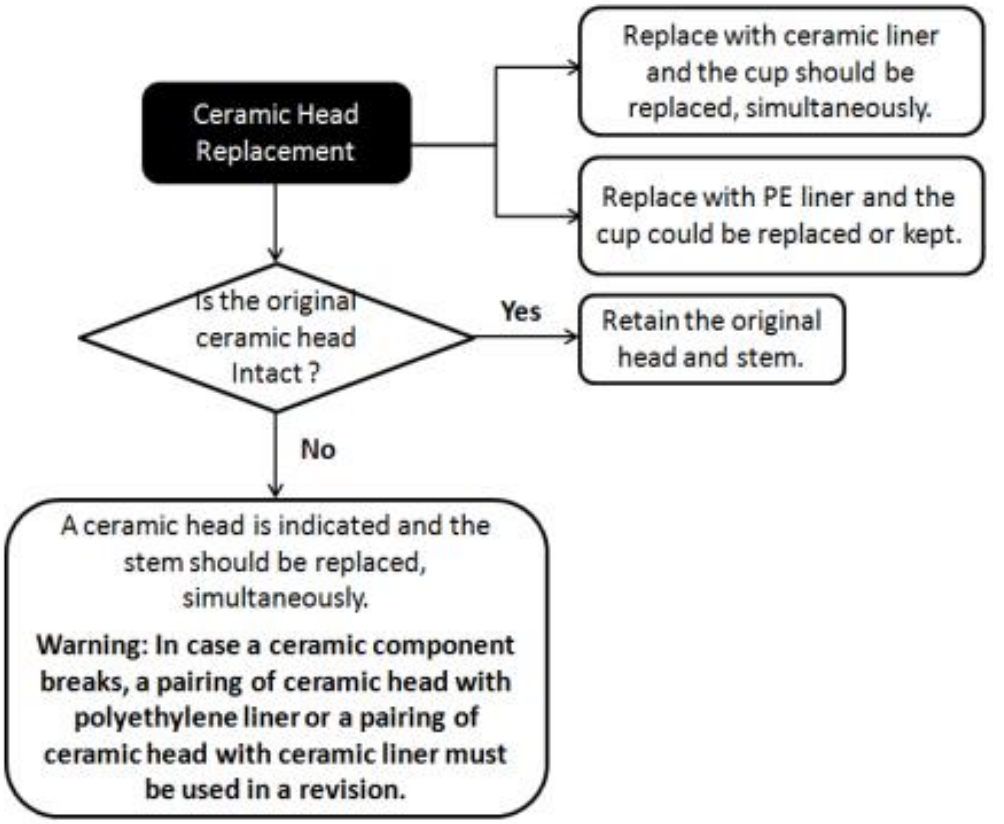


Fig. 6: Suggestions of ceramic combinations for a ceramic liner replacement.

STORAGE CONDITIONS

All implants should be stored at ambient warehouse conditions, within this recommended range: 7°C to 35°C at 30-85% relative humidity.

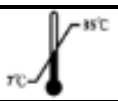
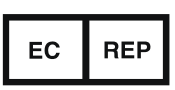
SAFETY INFORMATION IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT

This device components has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INFORMATION

For further information, please contact
United Orthopedic Corporation
No. 57, Park Ave. 2, Science Park,
Hsinchu City 30075, Taiwan.
TEL: +886-3-577-3351
FAX: +886-3-577-7156
Contact Information: unitedorthopedic.com/contact

SYMBOLS GLOSSARY

Symbol	Title of symbol	Description of symbol	EN ISO 15223-1
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can beidentified.	5.1.5
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3
	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
	Do not resterilize	Indicates a medical device that is not to be resterilized.	5.2.6
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8
	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
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2