English

Instructions for Use **SHARK CP PRO®**
Anterior Cervical Fixation System, which consists of plates and screws in various dimensions
Vertebral Column Fixation Systems (non-sterile)
CE mark in accordance with 93/42/EEC

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General safety instructions
The safety and proper functioning of the Bricon SHARK CP PRO cervical fixation system can only be ensured if the instructions for use and the respective surgical technique are considered and observed by the surgeon. The surgeon must be familiar with the entire complex of spinal problems. The surgical technique for the implantation of the Bricon SHARK CP PRO cervical fixation system can be learned most safely at a hospital familiar with this type of implants. The surgeon shall be solely responsible for any complications which may arise as a result of an incorrect indication, surgical technique or asepsis; neither the manufacturer nor the supplier of Bricon GmbH products can be held responsible in any such cases. The Bricon SHARK CP PRO System and the corresponding instruments are not suitable for use on the central nervous system.

NON STERILE

All implants and instruments of the Bricon SHARK CP PRO cervical fixation system are recommended and intended by Bricon GmbH as non-sterile. The implants are disposable products for single application on a patient.

Intended use
The Bricon SHARK CP PRO cervical fixation system is intended to help provide stabilisation of spinal segments as an adjunct to fusion of the cervical spine at the level C3 – C7 and employing a screw fixation at the anterior face of the cervical vertebral body.

Patient

Duty to inform the patient
Prior to the surgery, the patient must be instructed in detail on potential side effects. Refer to this instruction for use!
The patient must be informed about any factors influencing the life cycle and safety of the implant, also in special circumstances. This information is particularly important in order to minimise risks which may arise e.g. from high physical stress.
The surgeon shall document the consultation of the patient prior to surgery, including detailed records on the information provided to the patient. Conservative, non-invasive treatment alternatives are preferable to the use of implants.

Patient history record – "patient passport"
REF LOT
A "patient passport" shall be handed over to the patient after the surgery. All of the reference and lot numbers of the implants are used shall be documented in the corresponding patient documents in order to enable traceability.

Prior to surgery
Patient: Application area and requirements for surgery
- Patients with frequent or persisting cervical pain which becomes stronger under load.
- Patients suffering from pain symptoms which have persisted over a long period of time and increased in intensity in such a way that the pain radiates to other parts of the body.
- Patients suffering from severe cervicalgia (C3 – C7) resistant to conservative or any other surgical therapy, provided that the expected gain in quality of life outweighs the risk of long-term complications.
- Patients with degenerative spondylolisthesis of cervical spine.
- Patients with fractures at C3 – C7.

Bricon GmbH products may only be used in patients if the spinal section concerned is suitable for the insertion of an implant in terms of both anatomic aspects and structural quality and who will tolerate the implanted materials.
The surgeon shall inform each patient about the risks of an implantation.

Surgeon: Requirements for surgery
- Highly aseptic conditions in the operating room.
- Must be familiar-in the use of Bricon GmbH products in attention of the surgical technique.
- Complying with the Bricon GmbH surgical technique.

The surgery may only be carried out if the conditions mentioned above for both the patient and the surgeon are fulfilled!

Indications
- Degenerative disc disease
- spinal instabilities
- Tumors with additional ventral support
- Fractures with ventral support;
- Multi-segmental fractures with segmental fixation
- Post-traumatic deformities
- Adjacent segment instabilities
- Vertebral body fractures

Contraindications
Patients in an unfavorable medical or psychological condition that may worsen as a consequence of the surgery, require careful consideration by the surgeon.
- Pregnancy
- Infections
- Severe osteoporosis
- Severe spinal instabilities
- Severe vertebral body fractures
- Spinal tumours

Intended patient group
The product is to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Which application restrictions must be communicated to the patient?
The surgeon carrying out the operation shall inform the patient about the following application restrictions and risks which may affect the safety and performance of the implant:
- Tumours weakening the supporting structures
- Severe deformities of the joint concerned, which complicate the anchoring of the implant
- Repeated accidents with increased risk of fracture
- Seizure disorder (epilepsy)
- Infectious diseases with risk of joint manifestation
- Allergy against a material component of the implants (*see materials used*)
- High physical stress caused by work or sport
- Extremely obese patient

On the one hand, even a successfully implanted spinal support system is inferior to the natural, healthy anatomy (of the back). On the other hand, a spinal support system can be a beneficial replacement for a strongly altered, morbid spinal element because it removes pain and can help to achieve a high level of mobility and stability. Each spinal implant is subjected to minor wear and tear which cannot yet be influenced today. A spinal support system which has been stable following implantation can, nevertheless, become loose over time. Further surgery can become necessary as a result of wear and loosening. An infection caused by a spinal support system can have negative effects on the patient's health because the implant must usually be removed, which can result in severe invalidity.

Intended user
The Bricon products are intended to be used only by healthcare professionals. To ensure correct handling of the Bricon GmbH instruments and implants, the surgeon and user is responsible for the selection of the implants and instruments for the treatment and the operational use and also for appropriate training by Bricon GmbH personnel or personnel of an authorised distributor. The study of the surgical technique is an essential part of the training. The training shall be recorded by Bricon's personnel. A copy of the training record shall be left to the surgeon and the user.

Which implants and instruments must not be used?
Damaged, scratched, incorrectly treated implants, implants treated without approval and non-sterile implants. Implants which have already been implanted or been in contact with a patient, implants contaminated with blood/secretion must not be re-sterilised and implanted. The reconditioning of used implants entails a risk of infection and other hazards which may place the patient's health or life at risk; the responsible surgeon decides in this case accordingly.
Necessary instrument sets which belong to the SHARK CP system must be complete and in good condition for correct use.

Reclamations
Any customer or user of Bricon products who wishes to make a complaint or is dissatisfied with the product quality, identity, durability, reliability, consistency, safety, effectiveness and/or performance should notify the authorised distributor or Bricon GmbH directly. Should a Bricon product ever malfunction and cause or contribute to the death or serious injury of a patient, the distributor and Bricon should be notified immediately by telephone, fax or in writing. In addition to that such an incident has to be reported to the competent authority. When filing a complaint, please include the name and number of the component(s), the batch number(s), your name and address, the nature of the complaint and whether a written report from the distributor is requested.

Disposal
Used implants or implants that have come into contact with blood, soft tissue, bone or body fluids must not be reprocessed and reused and must be disposed of. The implants are made exclusively of biocompatible materials and are absolutely inert with regard to disposal. The implants can therefore be disposed of with the standard surgical waste in the hospital. Contamination residues on the implants may cause injury or infection to the patient or user.

Cleaning, disinfection, sterilisation, and storage
For the cleaning and disinfecting of the implants and instruments, a machine procedure (with a RDG (cleaning disinfector) and / or disinfector) should be used, if possible. A manual method, even using an ultrasound bath, should be used only in the case of non-availability of a machine process due to its significantly lower effectiveness. The use of a manual cleaning and disinfecting procedure must be carried out by an additional product and process-specific validation under the responsibility of the user. Pre-treatment should be carried out in both cases.

Pre-treatment at the point of use
Remove gross soil with disposable low–linting cloth/paper wipe
Inspect all instruments and Implants to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process

Containment and transportation:
No particular requirements. It is recommended that these instruments are processed as soon as is reasonably practical following use: In a tub with disinfecting solution or in a closed container (avoid the drying of blood and tissues).

Pre-cleaning
Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions. Soak soiled instruments for 5 minutes in the enzymatic solution *(e.g. 0,5% Gigazym)*. Remove instruments and rinse the instrument with cold tap water. Then scrub thoroughly with a soft brush; repeatedly flush any narrow lumens with a water jet pistol or an alternative product (> 30 sec. each) to remove all traces of blood and debris and cleaning reagent; pay close attention to any hard-to-reach areas, textured surfaces, or crevices. Dry the instrument after final rinse or proceed immediately with the automatic cleaning process.

Automatic Cleaning and Disinfection
The demountable instruments must be dismantled prior to disinfection and cleaning. All of the Bricon GmbH products must be handled with care because improper use or handling can cause damage and decrease the functional reliability of the products. Bricon GmbH products must be cleaned and disinfected prior to sterilisation. Cleaning and disinfection must be performed using a suitable washing apparatus. Do not overload the washer/disinfector. Be aware of the following:

1. 1 Minute Pre-cleaning: Cold Water < 40° C
2. 5 minutes cleaning at 55° C, 0,5% neodisher® MediClean forte
3. Neutralization 2 minutes (neododisher Z, 0.1%) with cold water < 40°C
4. 1 minute rinsing with demineralized water (VE Water)
5. Thermal disinfection, 5 min at 92 ± 2°C with demineralized water (VE Water, A_0-value acc. national requirements)
6. Automatic drying for 30 Minutes

- Main rinsing cycle: temperature 55 °C. Follow the instructions of the cleaning reagent manufacturer
- A0 – value, time, and temperature depending on the product classification in accordance with the German RKI guideline (guideline of the Robert Koch Institute) and preparation as per EN ISO 17664
- Cleaning agents and disinfectants which comply with national regulations (e.g. CE marking) and are also suitable for the cleaning and disinfection of medical products consisting of stainless steel, PEEK, and titanium (Ti6Al4V)
- Prevent neutralisation
- For final cleaning, the products must be rinsed with sterile or almost germ-free water
- If devices are not completely dry after automatic cleaning/disinfection, use filtered air for final drying

Cleaning inspection
Inspect all instruments and Implants to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

Packaging of individual instruments for sterilization
For double packaging of individual instruments, commercially available medical steam sterilization bags of appropriate size can be used. Make sure that the inner bag is large enough to hold the instrument completely without damaging the sealing but small enough to fit into a second bag without compromising the integrity of the entire package. Individual instruments can be packaged in medical steam sterilization fleece. The package should be prepared with a double layer of fleece.

Instrument trays and cases with defined, preconfigured layouts
In the areas identified for specific instruments, only instruments specific to these areas may be used. Only instruments manufactured and / or marketed by Bricon should be placed in Bricon instrument trays. These validated reprocessing instructions do not apply to Bricon trays containing instruments not manufactured and / or marketed by Bricon.

Universal instrument trays and cases without delimited, preconfigured layout should only be used under the following conditions
Each instrument which can be disassembled must be disassembled before being placed in the tray. All instruments must be arranged in such a way that the steam can reach all instrument surfaces. Instruments should not be stacked or contact each other. The user must ensure that the instrument tray is not tilted or the content slides after the instruments have been placed in the container. Silicone mats and brackets can be used to keep devices in place.

Sterilisation
The spinal implants and instruments are **delivered in non-sterile** packaging and must be **prepared and sterilised by the hospital** prior to use. The following sterilisation conditions should be observed by the surgery team:
Pre-Vacuum Steam Sterilisation (3 Pre-Vacuum Steps)

- Temperature: 134°C
- Time: 5 minutes
- Dry Time: 45 minutes

Note: The instruments can be subjected to any number of sterilisation, cleaning, and disinfection cycles. Bricon GmbH does not assume responsibility for Bricon GmbH products used in surgeries without being cleaned, disinfected, and sterilised in accordance with the present instructions. Observe the Treatment Instructions provided by Bricon GmbH, RKI list, Instrument Treatment Working Committee, EN ISO 15883-1, EN ISO 15883-2, EN ISO 17664, EN ISO 17665-1!

Storage and treatment of the implants and instruments
All of the Bricon GmbH products must be handled with care because improper use or handling can cause damage and decrease the functional reliability of the products. Spinal implants are sensitive to mechanical and chemical impact.
Storage conditions: The products must be stored under clean, dust-free, cool, and dry conditions and protected against sunlight and chemicals. Spinal implants must be stored in an unopened, original packaging.
Protective packages may only be removed immediately before sterilisation. Spinal implants must not be mechanically treated or otherwise modified.

Surgery

Notes concerning surgery
The surgery team shall undertake to ensure that only cleaned, disinfected, and sterilised products are present in the OR. The operation must be precisely planned on the basis of the X-ray diagnostic findings. In addition, the specific Bricon SHARK CP PRO instruments must be used for the preparation and placing of the implant. The proper functioning of the instruments and implants must be briefly checked prior to surgery. Excessive forces acting on the implant can lead to an injury of the patient.

Surgical technique
When inserting the implant, the trained surgeon must strictly observe the related surgical technique. Only use suitable Bricon instruments for the implantation. The implants must not be inserted in combination with third party implants or instruments. Bricon Spine System implants may only be implanted as integral parts of the Bricon Spine System used as vertebral column fixation system. The surgeon must determine during surgery, whether plates or rods are to be used. The size of the implant must also be determined by the surgeon based on the size of the vertebral bodies and the bone and surrounding conditions, during surgery. After the implantation, the correct fit of the implant must be checked by means of an X-ray image and, if applicable, a functional test.

Important factors for successful surgery
Correct anchoring is crucial for the stable and long-lasting positioning of the implants. The **following deficiencies** can result in e.g. loosening of the implant and complications: excessive weakening of the bone structure, applying excessive force when placing or fixing the implant with a potential risk of burst fractures or bone demolition, non-compliance with the surgical technique.

Re-operation – removal of the implants
Suitable Bricon instruments must be used to remove the implants. In case of excessive bone or fibre growth after the first surgery, there is a risk of the removal instruments and implants being exposed to additional stress. This can lead to fractures in the zone of operation. For this reason, bones and/or soft tissues, including the tissue surrounding the implants, should be removed prior the removal of the implants.

Postoperative

Patient – postoperative behaviour
The patient must avoid fast and incorrect movements postoperatively. The success of the operation can also be put at risk by falls, sport or impact injuries (avoid jumping, marathon, jerky movements, etc.).

Physician – postoperative follow-up
Each patient with a spinal support system requires consistent follow-up examination by the surgeon or a competent specialist physician. This is extremely important as signs of wear or loosening of the spinal support systems can already be diagnosed before the patient with a spinal support system shows symptoms. If complications are diagnosed at an early stage, countermeasures can be taken. In particular, a re-operation at an early stage can lead to better results provided that progressed loosening has not yet resulted in alarming complications. The patient must be advised to contact his/her surgeon immediately even in case of minor spinal changes. In addition, the implants must be checked after severe falls or impact injuries. If annual clinical follow-ups are not possible, an X-ray should be sent to the surgeon for examination at least once a year. This ensures that undesirable developments and problems can be detected at an early stage.

Side effects/postoperative complications
The following complications can occur and require the special attention of the treating physician:

- Loosening of the implants as a consequence of changed load transmission conditions
- In most cases, the implants can loosen as a consequence of one or several of the conditions mentioned above, but also in case of insufficient anchoring
- Fracture of the vertebral body and/or tissue reaction to the implant
- Bone fractures as a result of one-sided or general stress or a weakened bone substance
- Early or late infections
- Dislocation
- Subluxation
- Restricted range of motion for the patient
- Undesired reduction or extension of the extremity concerned as a result of improper positioning of the implant
- Temporary or permanent nervous lesion as a result of pressure impact or haematoma
- Cardio-vascular diseases including venous thrombosis
- Pulmonary embolism and cardiac arrest
- Wound haematoma and delayed wound healing
- Tissue reaction as a result of an allergy to the implanted material, special metal or huge quantities of abrasion particles

Materials used
The material used is indicated on the corresponding product label. The implants consist of titanium (Ti6Al4V in accordance with ISO 5832-3 and ASTM F136). All of the implants of the Bricon SHARK CP PRO cervical fixation system are recommended and intended by Bricon GmbH as non-sterile disposable products for single application on a patient. All of the instruments consist of stainless steel, hand pieces partly include a silicone base, trays, support modules, and transport boxes consist of stainless steel, PTFE, and aluminium, cleaning and reconditioning as described under *Cleaning and disinfection*.

Material resistance
The products are not resistant against strong organic, mineral and oxidizing acids, strong bases with a pH value >12, solvents such as alcohols and benzine, bromine, chlorine, fluorine, iodine.

Information
Bricon GmbH only accepts return shipments from the hospital accompanied by a *sterilization certificate* or in the original packaging! For more detailed information please refer to a representative of the Bricon GmbH or contact us under info@bricon.com.
Refer to the type designations and article numbers!

WARNINGS

1. THE SELECTION OF THE CORRECT IMPLANT SIZE IS VERY IMPORTANT
The probability of a satisfactory fixation is increased by the selection of the correct size, form, and quality of the implant, while the correct selection may support the minimising of risks, size and form of the human bones, leading to restrictions regarding the size, form, and firmness of the implants. In case of internal fixation systems consisting of TITANIUM or PEEK, the same level of activity cannot be assumed as for fixations with normal, healthy bones. No implant is able to stand the complete weight load without supporting measures for an indefinite period of time.

2. IMPLANTS MAY BREAK IF THEY ARE SUBJECT TO AN INCREASED LOAD FOLLOWING DELAYED OR UNCONSOLIDATED STIFFENING
Internal fixator systems support the load distribution to ensure the correct orientation until the normal recovery. In case of a lack of healing or delayed healing, the implant may break due to the fatigue of the materials used. The level of stabilisation, the weight load, and the level of activity are decisive for the life cycle of the implant. Notches, scratches or a bending of the implant during the surgery may also contribute to an early failure. The patient should be informed in detail about the risks of an implant failure.

3. THE USE OF DIFFERENT METALS MAY RESULT IN CORROSION
There are numerous forms of corrosion damage and some of them occur in surgically implanted metals. A certain corrosion level occurs regarding all of the implanted metals and alloys. In general, the effect of the corrosion for the metal implants is very minor due to the present passive surface coatings. If different metals, such as titanium and stainless steel, come into contact, the corrosion process of stainless steel accelerates and the material is affected more. Corrosion often accelerates the fractures of the implant due to the fatigue of the material. The amount of the metal components delivered into the body also increases. Internal fixations as with cages, screws, rods, hooks, plates, etc., coming into contact with other metal objects shall consist of similar materials or materials that are compatible with each other.

4. SELECTION OF THE PATIENTS
The following factors may be very important for the selection of the patient for internal fixator systems and the future success of the treatment:
A. The patient's weight. An obese or adipose patient can stress the implant so much that a failure is probable and the surgery would fail.
B. The patient's profession or level of activity. If the patient's professional or private activities include heavy lifting, muscle strain, twisting of the body, repeated bending, stooping, running or manual work, these activities should be avoided until the complete healing of the bone.
Even after complete healing, it is possible that the patient will not be able to successfully perform these activities again.
C. Senility, mental illness, alcohol consumption or drug abuse. These conditions may contribute to the fact that the patient ignores necessary restrictions and precautions in connection with the implant which may result in an implant failure or in other complications.
D. Specific degenerative diseases. In some cases, a degenerative disease may have advanced to the extent that the expected lifetime of the product is significantly reduced. In these cases, orthopaedic aids may only delay the degeneration or temporary stop.
E. Foreign body sensitivity. The physician is informed that it is not possible to completely exclude a possible sensitivity or allergic reaction by means of a preoperative test. Even if the implant is placed in the body for a certain time, the patient may suffer from hypersensitivity or an allergy.
F. Smoking. A higher rate of pseudoarthrosis has been detected in smokers following surgical interventions with bone implants. Furthermore, a diffuse degeneration of the intervertebral disks has been observed in smokers.
The progressive degeneration of adjoining segments caused by smoking may result in a later clinical failure (periodic pain) even if there was successful bony stiffening at first, and then a clinical improvement.

PRECAUTIONS

1. SURGICAL IMPLANTS SHALL NEVER BE REUSED
An explanted metal or PEEK implant shall never be used again. Even if the implant seems to be undamaged, it may reveal some small defects and invisible excessive strain that may result in premature wear.

2. THE CORRECT HANDLING OF THE IMPLANT IS VERY IMPORTANT
Metal implants shall only be formed with corresponding equipment. The surgeon should avoid notches, scratches or bending of the product while forming it. Changes of the form result in damage of the surface coating and to an invisible excessive strain that may be the basis of a later implant fracture. Bending the screws significantly decreases the lifetime and may result in a premature failure.

3. REMOVAL OF THE IMPLANT FOLLOWING HEALING
If the system provokes a change of the medical condition of the patient because of different reasons after the insertion, such as an allergy, fracture etc., it should be decided after a previous consultation of the treating physician if the implant(s) must be removed. If, depending on the diagnoses, the implants do not need to be removed, the following complication may occur alone or in combination:
(1) corrosion with a local tissue reaction or pain; **(2)** change of the implant position and resulting injuries; **(3)** risk of additional injuries caused by a postoperative trauma; **(4)** bending, loosening and/or fracture with complicated or impossible removal; **(5)** pain, discomfort or nonphysiological sensations due to the present product; **(6)** a possibly increased risk of infection, and **(7)** bone loss due to load shielding. The physician should carefully consider the risks and benefits prior the removal. After the removal of the implants, a renewed fracture or sintering should be avoided by adequate postoperative care.
In case of older or less active patients, the surgeon may do without a removal of the implant to exclude the risks in relation to a second surgery.

4. THE PATIENT SHALL BE INFORMED AS DETAILED AS POSSIBLE
The postoperative care and ability of the patient to comply with instructions are the most important aspects regarding a successful bone healing and/or fusion. The patient must be aware of the restrictions of the implant and be instructed to avoid or restrict physical activities, in particular lifting and twisting movements and participation in sports. The patient must be aware that a metal or PEEK implant is not as strong as a normal, healthy bone, and that in case of an excessive load – in particular in case of an incomplete bone healing – loosening, bending and/or fractures may result. Dislocated or damaged implants may move and damage nerves or blood vessels. An active, invalid or demented patient who cannot use the supporting walking aids accordingly is specifically at risk during the postoperative rehabilitation. By means of the stabilisation of two vertebral bodies by implants as per a corresponding indication, the force distribution of the moving forces to be acquired changes to the vertebral bodies above and below.
Due to the increased load of the connected segments the patient may suffer further damage regarding the intervertebral disks and bony structures so that it is possible that the patient has further problems with the connected segments after the complete healing and that a renewed surgery will be required. Possible problems, pain as well as follow-up treatments/damage must be discussed with the patient in detail in advance.
Conservative, non-invasive treatment alternatives are preferable to the use of implants.

5. CORRECT PLACING OF THE SPINAL IMPLANT(S)
Due to the proximity of vascular and neurological structures to the implant site, there is a risk of severe or fatal bleeding as well as neurological damage when using this product. Severe or fatal bleeding is possible if the larger vessels erode, are punctured during the implantation or are damaged due to a fracture or migration of the implants after the implantation or if the vessels are eroded in a pulsatile way due to a near apposition of the implants.

POSSIBLE SIDE EFFECTS
- Bending or fracture of the implant.
- Loosening of the implant.
- Metal hypersensitivity or foreign body allergy.
- Early or late infection.
- Bad or delayed stiffening of fractures.
- Decrease of the bone density caused by load shielding.
- Pain, discomfort or non-physiological sensations caused by the present implant.
- Consequential damage regarding/in connection with the connected segments.
- Nerve damage caused by a surgical trauma or the present implant Neurological discomfort including the malfunction of the bowel and/or bladder, impotence, retrograde ejaculation and paraesthesia.
- Bursitis.
- Paralysis.
- Ruptures in the dura occurring during the surgery may require a renewed surgical intervention to recover the dura and result in a persistent leakage of cerebrospinal fluid or a fistula and, among others, meningitis.
- Death.
- Vascular damage caused by a surgical trauma or internal fixation. Vascular damage may result in life-threatening or lethal bleeding.

LEGEND			
REF	REFERENCE	LOT	LOT NUMBER
	CAUTION	NON STERILE	NONSTERIL
	FOLLOW THE INSTRUCTIONS FOR USE	QTY	QUANTITY
	FOR SINGLE USE ONLY	CE	CE LABELLING
	KEEP AWAY FROM DIRECT SUN	Rx	PRESCRIPTION / FOR PROFESSIONAL USERS ONLY
	MANUFACTURER		