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7999.902.003.01/191
Instructions for Use
Instrukser for bruk
Bruksanvisning
Brugsanvisning
使用说明书
Οδηγίες χρήσης
Инструкция по применению и дополнительной информации

For observations on physicians and OP personnel especially

Print 06/19

ENGLISH

Manufacturer: Synthetis AB
Synthetis AB
Ingemansgatan 2a · 20159 Hannover · Germany
www.synthetis.com · E-mail: info@synthetis.com
Telephone: +49 511 270 413 59
Fax: +49 511 270 413 79

SYNTELLIX

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1. General

It is absolutely essential that you fulfill all requirements described in these instructions and take into consideration the special information described in them. If not, these products may not be applied for the clinical use.
Keep these instructions for future reference. Make them available to all persons who are using these products. If you give these products to other persons, also give them all the instructions.
These instructions cannot replace the actual user in terms of training, caution exercised and knowledge of the current state of technology. We therefore ask you to ensure that the latest version of these instructions (electronic version) of the instruments, regulations, standards and recommendations (e.g. those of the RKI or the AKI, see 15. Standards/References) are the medicine, they document the current state of technology and are of significant for our products and that the user must observe for each product. Our products are in line with the state of the art. We do not take any responsibility for any other use of our products than that in the legal regulations and recommendations.
READ THROUGH ALL APPLICABLE INSTRUCTIONS FOR USE VERY CAREFULLY BEFORE REPROCESSING AND USING A PRODUCT FOR THE FIRST TIME!

2. Product description

Synthetis AG instruments are intended for use in trauma surgery and orthopaedics. Reusable instruments are delivered non-sterile and must be cleaned and sterilized by the user before initial use and after each use. Before they are cleaned for the first time, original packing and protective caps must be removed completely.

3. Choice and application of instruments

Synthetis AG instruments are only to be used for the intended use as specified below. The responsibility for selecting the instruments and their intended use lies with the attending physician. The attending physician and all other personnel involved in handling products are responsible, within their areas of activity, for possessing the appropriate knowledge on the product, its intended use and the relevant laws. This also applies to the correct product handling and prevents health risks and/or risks to patients, users or other third parties.
Prior to any surgery, the user must verify that the instruments are in perfect condition and have been adjusted to work optimally with one another and that the implants are complete. Only those instruments that are clean may be used for trauma surgery.
Sources for information on products include the corresponding product catalogues, videos, specialist literature, recommendations, specialist product consultants, work groups, seminars, specialized courses, product training, etc. Our product range includes a wide range of products, including training on product handling and instruments using products for children.
The surgical procedure must be taken from the product information for the implantation device, and also selected based on the current state of medical knowledge and experience of the attending physician. Implants and instruments are not to be used beyond the specified and recommended areas of use and in the prescribed manner. Documents can be downloaded from www.synthetis.com or as a PDF file or obtained from your medical device consultant.

1. Combination notice

Synthetis AG does not assume liability for any complications that may occur due to the combination of products supplied by other manufacturers.

2. General warnings and precautions

Products are delivered NON-STERILE!
After you receive your product, check it for identity, completeness, intactness and functionality before you actually reprocess it for use.
Do not use products that are damaged or show signs of damage to the instrument. Damage to the instrument can lead to injuries to the patient and on an instrument can cause its material to be weakened and can lead in turn to intraoperative breakage. Such a product, the instrument, must be examined for damage before and after each use to ensure that it is functionally reliable and safe to prevent injuries to patients, users or third persons. Damaged instruments must be immediately taken out of use and sent back to the manufacturer.
Damaged instruments with unrecognizable indications and markings, such as, for example, a lot number, may not be used for the first time or re-used. In particular, it must be assumed that the load capacity of an instrument without breakout is undamaged and in perfect condition, that the connections between the individual parts of the instrument are straight (risk of deformation) and the instrument/implant can be connected without any problems.
We assume no responsibility for the repair of an instrument after it comes into contact with or is used on patients with highly infectious, generally fatal diseases (e.g. Creutzfeldt-Jakob disease [CJD] or any of its variants). Given this context, please remember that it's possible for even unused instruments to become unusable and need to be disposed of in accordance with your own responsibility. Instruments are generally disposed of in accordance with current RKI guidelines.
The user (reprocessor) is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in his/her own facility achieves the desired results. This generally applies to reprocessing using validated processes. It must be ensured by the reprocessor and/or deviation by the user (reprocessor) from the instructions provided should necessarily evaluated for its effectiveness as well as any possible unfavorable consequences.

3. Processing of instruments

The instruments must be cleaned and steam-sterilized before each use. Before the first clinical use, the effectiveness of cleaning and protective devices must be completely removed and disposed of. Cleaning and disinfection in the original packaging is not possible. Synthetis AG provides instruments that are exclusively thermoduric – machine cleanable and thermally disinfectable – and tested prior to the manufacturer's shipment.

Selection of cleaning agent

A mild alkaline cleaning agent should be used in order to avoid corrosion damage. Instruments must always be flushed sufficiently using demineralized water (DI water). Only a neutral rinsing agent (e.g. vinegar) may then be used in the rinsing process, using demineralized water with a neutralizer (e.g. Mucasol 2 or Neodisher 3 ULTRA). In this case, manufacturer instructions for the cleaning agent, dosage and other additives must also be observed.
The following cleaning agents and disinfectants are not suitable for cleaning instruments:
- acidic cleaners or oxidizing acids
- organic solvents (e.g. acetone, ether, alcohol, benzine)
- oxidizing substances (e.g. peroxide)
- halogens (chlorine bleaches / bromine compounds)
- aromatized, halogenated hydrocarbons

Preparation before cleaning

Instruments must be deposited properly during surgery in order to prevent damage to the instrument and injuries to the surgical staff. Instruments already after use and after transport especially flexible modules must be removed from the product no later than two hours after use. Cold running water or a disinfectant wipe can be used for this purpose. The disinfectant should be free of aldehydes and has been tested for effectiveness against HIV, HBV and HCV viruses. Coagulated physiological solutions using proteins and blood can lead to corrosion.
As far as possible, instruments must be disassembled into their individual components, hinged to be hygienic.
Only a soft brush or a soft, clean cloth may be used for manual cleaning. Brushes and cleaning agents must be used in accordance with the manufacturer's instructions.

Precleaning in ultrasonic bath

Instruments being manually cleaned must always be cleaned in an ultrasonic bath. Precleaning can also be used to support a machine cleaning process. This is appropriate if the instruments are very large, heavy and cannot be disassembled. To do this, instruments must be placed in a suitable basket and immersed in a bath of cold water containing additive (solution or powder) and left for the specified time (see manufacturer specifications, e.g. 0.5% Neodisher® Mediclean, room temperature). Depending on the degree to which the instruments are contaminated, the exact time can be adjusted to be between 10 minutes and 30 minutes. Instruments with complex surfaces and/or with blind holes should be cleaned in an ultrasonic bath with a suitable cleaning agent. Instruments in general, all Synthetis AG instruments are appropriate for treatment in an ultrasonic bath. Instruments with hinges, sliders, or other moving parts or components made of silicone do absorb the effect of the ultrasound.

Manual cleaning and disinfection

a) Cleaning
Rinse off any non-metallic brush, brush the entire outside surface of the instrument, ensuring that no soiling remains, and then rinse it for approx. 10 seconds under running cold water. Instruments can be handed especially carefully when rinsed. Cleaning/disinfection in the ultrasonic bath is not required when using a hound nylon brush, the brush should be moved back and forth at least 10 times. Use a brush with a suitable diameter for hinges, couplings and joints. Rinse for 10 times under running water.

b) Disinfection
Instruments must be treated completely in a disinfectant bath (solution in water in accordance with disinfectant manufacturer specifications, e.g. 0.5% Neodisher® Mediclean, room temperature). Instruments must not come into contact with other instruments. For instruments with cavities, ensure that the disinfectant solution is in contact with the inner surface using a syringe. The specified exposure time must be adhered to. It is also recommended that the parts be moved by hand in order to ensure the inner surface is flushed and that any air bubbles are removed from the bath, they must be flushed using cold DM water (10 minutes).
Rinse off the disinfectant in the ultrasonic bath (not free-cloth. Instruments must be dried using a lint-free cloth.
The manual cleaning process was validated using 0.5% Neodisher® Mediclean, the machine cleaning process was validated using Korsolex Plus (3% solution).

Machine cleaning and disinfection

The washer-disinfector (WDD) you use must meet EN ISO 15883-1 requirements. Use only chemicals that are suitable for use in a WDD and are approved for it.
Place or insert disassembled instruments in the appropriate receptacle of the WD. Unless storage in the implant kit specifies otherwise, product must be cleaned in open position.
Remove implants and instruments as soon as possible after the end of the WD. Unless storage in the implant kit specifies otherwise, product must be dried in open position.

Phase	Minimum Time	Comments
Pre-rinse	2 min.	cold water with UHT softener
Cleaning	5 min.	Water 35°C (at 5°C of the cleaning additive)
Neutralization	1 min.	Water with neutralizer (Mucasol 2)
Refloat	1 min.	With warm water (max. 35°C ± 3°C)
Thermal disinfection	5 min.	93°C–142°C with DM water; no additives
Drying	30 min.	110°C–142°C

1. Removing instruments from WD after program end.
2. A high-pressure cleaner (max. 10 bar) is necessary to include a neutralizing step in the washing process, using demineralized water with a neutralizer (Mucasol 2 or Neodisher® Mediclean) on concentration treatment time, temperature and material compatibility must always be observed.
The process was validated using the Neodisher® Mediclean (0.5% solution), without the addition of a neutralizer.

7. Examination, assembly and care

Instruments must be checked for any room temperature after cleaning and **afterwards** visually for any soiling, damage, and signs of corrosion and non-functioning parts. Products must be reprocessed again if any residue is visible. The user must have the instruments checked, serviced, lubricated and contaminated instruments.
Only fully functional and assembled. An instrument with joints that will that is suitable for autoclaving and shows a proven biocompatibility must be used. Instruments with joints must be opened for sterilization. The instruments can also be packaged in such a way that they are delivered for this purpose. Plastic surfaces should not be treated with products for instrument care.
Among other items, a final examination of instruments should include:
- visible integrity (especially in cutting instruments) as well as functional areas
- completeness of multi-part instruments
- operability of moving parts
- proper functioning

The products prepared in this way must be placed in the corresponding location in the implant kit. This kit must be packed in a sterile barrier system as specified in DIN EN 868-5 and then sterilized (steam sterilization, e.g. in accordance with DIN EN 13060 and DIN EN 285 respectively be used for this purpose.
The following parameters are recommended:

Sterilization Temperature	Sterilization Time
134°C (273°F)	5 min.

There must be a sufficient period to dry the instruments (minimum drying time of 30 minutes).
Sterilization time can be increased up to 18 minutes, to comply with the recommendations of the RKI (see 15. Standards/References) for validating sterilization techniques and sterilization equipment lies with the user.
The process was validated using a triple fractionated pre-vacuum method at 134 °C for a minimum of 5 min.

7. Additional instructions on cleaning and sterilization

- Cleaning and disinfection agents can have a corrosive effect on instruments if the instruments are not rinsed properly and/or the recommended described and instruments are maintained adequately. It must be ensured that it is impossible for any cleaning and disinfection agents to be carried through insufficient flushing and/or neutralization. These residues some cleaning and disinfection agents can lead to, for example, in the form of corrosion and discoloration. Synthetis AG does not allow its instruments to become damaged. It is absolutely essential for instruments to be examined after cleaning and care. Products that been stored for repeated sterilization has a negative effect on the proper functioning and lead to breakage.
The end of a product's service life is determined by its proper and careful use as well as damage through use. Since instruments are only used by qualified personnel, the responsibility for evaluating the usability of instruments lies with the surgeon.

8. Storage

Brand-new instruments must be stored dry (humidity 15 %–90 %) and protected against dirt and UV rays. Storage parameters for other instruments depend on the specific guidelines established by each medical facility.

9. Disposal

Products and/or preparation instruments must be disposed of properly. The applicable guidelines of the specific hospital operator apply in this regard.

10. Repair

Goods may only be returned if they are in a hygienically safe condition. The prerequisite is a complete decontamination of the product.

11. Material and marking

Synthetis AG instruments are composed of stainless steel according to EN ISO 7153-1 and can be combined with following components:
- coated light metals such as aluminum and titanium
- polymers such as PPSU, PEEK, silicone, HDW, POM-C and PTFE glass

Cleaning

Laser marking and/or colour coding can be used to mark instruments. In addition, Synthetis AG uses laser marking to mark implants and implant components. Laser marking and/or colour coding can be used to mark instruments. The marking process was validated using 0.5% Neodisher® Mediclean, the machine cleaning process was validated using Korsolex Plus (3% solution).

Disinfection

Marking and/or colour coding can be used to mark instruments. In addition, Synthetis AG uses laser marking to mark implants and implant components. Laser marking and/or colour coding can be used to mark instruments. The marking process was validated using 0.5% Neodisher® Mediclean, the machine cleaning process was validated using Korsolex Plus (3% solution).

Sterilization

Marking and/or preparation instruments must be disposed of properly. The applicable guidelines of the specific hospital operator apply in this regard.

12. Scope of delivery/shipments

Goods may only be returned if they are in a hygienically safe condition. The prerequisite is a complete decontamination of the product.

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Sterilization

Marking and/or preparation instruments must be disposed of properly. The applicable guidelines of the specific hospital operator apply in this regard.

14. Warranty

Synthetis AG assumes responsibility for proper cleaning, disinfection and sterilization of products when the recommended procedures, instructions, including any restrictions, must always be observed. Synthetis AG does not assume any liability for damage, defect, fetch free products, and our products are designed and manufactured to meet the highest standards of quality and safety. Our warranty and guarantee rights are void if we have not been informed of any incidents that occurred during the use of our products.

General comments

- Only use the instruments with the corresponding implant must be used for the intended purpose and in accordance with the instructions.
- The greatest caution must be exercised when screwing-in a bone implant mechanically, both to prevent mechanical and thermal damage to the bone and to prevent injuries to the user. Use only a torque limiter and a suitable screwdriver for this purpose.
- It is extremely important when using drill bits/counterbores/taps to ensure that the cutting edge is sharp and undamaged. Use only a sharp cutting edge to prevent additional damage to the implant and bone. Use only a sharp cutting edge to prevent additional damage to the implant and bone. Use only a sharp cutting edge to prevent additional damage to the implant and bone. Use only a sharp cutting edge to prevent additional damage to the implant and bone.
- Constant feed pressure must be applied when using drill bits/counterbores to avoid possible thermal damage to bones and tissue (necrosis).
- The risk of breakage is significantly reduced by maintaining a slight axial guidance of instruments.
- Do not bend implants or the counterscrew(drill) in combination with high rotational speeds, as this can lead to implant breakage. Implant fractures can lead to temperatures in the bone of greater than 47 °C. This can lead to irreversible damage to the bone. Use only a sharp drill to prevent bone necroses and subsequent loss of the implant-bone interface.
- Implantation instruments are not suitable for implantation of implants. Classically cut screws, normally diamond cut bone chips can be fished and rinsed.
- The use of dulled drills/counterscrews increases the risk of thermal damage.
- Drill must always be used with protection sleeves or drill guides in order to ensure that the instrument is mechanically guided through an impaired bone tissue.
- Bone cuts, any complications which do arise are not directly connected to the use of a rotating instrument but are caused more by inadequate cooling, too high a feed pressure, too high a rotational speed, too long a drilling time, too little or no irrigation, or a blunt drill bit. Bone cuts are only fixed to drive units. Only activate the rotating instrument when the working area is in place and fixed. Do not touch rotating instruments. Do not touch the rotating instruments. Do not touch the rotating instruments. Do not touch the rotating instruments.
- If there is a risk of sharp and pointed instruments penetrating the packaging, particularly suitable precautions must be taken or appropriate packaging.

9. Sterilization

Instruments can be sterilized by the physician of energy powered instruments makes it possible to avoid patient injury. There are no contraindications in this respect.

Drill bits, counterscrews and taps are not suitable for use in the central sterilization.

Combination products

In most cases, drills, counterscrews and taps are adjusted to the given drill/counterscrew/tap diameter. Only the corresponding drill/counter screw or guide wires can also be used for cannulated drills and counterscrews as a guide wire. Cannulated drills and counterscrews can also be used and adjusted to the given diameter using protection or holding sleeves.

Instrument Care

Instruments with joints, hinges, sliders and taps can be connected to lubricate drills or hand grinding is a suitable.

Disinfection

Screwdriver blades fit to the corresponding bone implant recesses (hexagonal 3D or serrated 3D).

- Drill bit example, art.-no. 9020.030
- 3D Counter example, art.-no. 9020.021
- 3D Counter example, art.-no. 9020.031
- 3D Counter example, art.-no. 9020.041
- 3D Counter example, art.-no. 9020.051

Vi: Application example: Drill bit 715 for quick coupling art.-no. 9020.030, with double drill guide art.-no. 9020.033 and guide wire art.-no. 9020.042

Vi: Quick coupling

Vi: Tap example: art.-no. 9020.022

10. Storage conditions for instruments

Intended use

Synthetis AG instruments are used to determine the bone implant length required for an implant. Here, the required bone implant length is taken from a scale on the measuring rod.

The maximum tile of measuring instruments is 3 years.

Measuring instruments are not sterile.

Measuring device (VX)

These are used to measure the length required for drilled bone implants. Length is determined by pushing the measuring rod up to the bone over the drilled hole. The length can be read off the measuring rod using the total length of the drill hole (DIAMAX DIAMAX).

Depth Gauge (X)

Depth gauges are used to measure hole depths within the bone. Depth Gauges usually consist of a measuring rod (X), a rod guide sleeve (X, 2) and a scale (X, 3). The depth of the drilled hole is determined by pushing or depending on the application. To measure the hole depth, the measuring rod is pushed through the rod guide sleeve until it touches the bottom of the hole. The measuring rod is then pulled back through the hole and hooked to the for cortex with the hook of the measuring rod (biofocal hook). The rod guide sleeve is moved back to the scale by pushing. Alternatively, the measuring rod can be pushed through the hole and hooked to the bone cortex.
The accuracy of the scale is 1 mm.

Contraindications

This measuring device as well as all other measuring instruments comes into contact with the human body temporarily (< 60 min) during the operation. There are no known contraindications.

Cannulated instruments must be cleaned and disinfected using the corresponding cannulation pin. Cannulation pin is necessary using a brush that fits tightly in the cannulation. In addition, cannulated instruments being manually cleaned must be cleaned in an ultrasonic bath. Synthetis AG only ensures that the cannulation is treated out. To do this, instruments must be cleaned in the ultrasonic bath and disinfected.

General comments

- Only use the instruments with the corresponding implant must be used for the intended purpose and in accordance with the instructions.
- The greatest caution must be exercised when screwing-in a bone implant mechanically, both to prevent mechanical and thermal damage to the bone and to prevent injuries to the user. Use only a torque limiter and a suitable screwdriver for this purpose.
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- Drill must always be used with protection sleeves or drill guides in order to ensure that the instrument is mechanically guided through an impaired bone tissue.
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TÜRKÇE

Üretici: Synthetis AG
Synthetis AG
Ingemansgatan 2a · 20159 Hannover · Almanya
www.synthetis.com · E-posta: info@synthetis.com
Telefon: +49 511 270 413 59
Faks: +49 511 270 413 79

SYNTELLIX

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Ek: Ürüne Özel Talimatlar

1. Genel Hususlar

Bu talimatlarda yazılanlara tam olarak uyulmalıdır ve özel bilgilerin uygulanmasına dikkat edilmelidir. Aksi takdirde ürünler klinik kullanım amacıyla uygunluk sağlamaz.
Bu talimatlar ileride kullanmak üzere saklanmalıdır. Ürünlerin kullanımı ile ilgili tüm kişilerin bu talimatlara ulaşmasını sağlayınız. Ürünleri diğer kişilere ya da kullanıcılara ulaştırmanız gerekiyorsa bu talimatlar da ürünlerle birlikte verilmelidir. Bu talimatlar, kullanıcıyı eğitim, dikkatli olma ve güncel teknik bilgiyi ikame etmez. Bu nedenle, ürünlerin ve bu talimatlar (elektronik versiyon) ile ilgili olan güncel standartlar, yönetmelikler ve tavsiyelerin (ör. RKI veya AKI'nin talimatlarına bakınız, 15. Standartlar/Referanslar) ürünlerinin kullanıcısı tarafından sürekli olarak gözetilmesini ve uygulanmasını sağlamanızı rica ederiz. Ürünlerimiz güncel teknik bilgiyi temsil eder ve ürünlerimiz ile ilgili olarak yasal düzenlemelerde ve tavsiyelerde belirtilen hususlar ve talimatlar dışında herhangi bir kullanım amacı ile ilgili herhangi bir sorumluluk kabul etmiyoruz.
OKUYUNUZ VE BİLİNÇLİCE UYGULAYINIZ ÜRÜNÜN İLK KULLANIMI ÖNCESİNDE!

2. Ürün Açıklaması

Synthetis AG aletleri, kullanım amacına göre travmatik ve ortopedik cerrahi tedavisi amaçlanmıştır. Tekrar kullanılabilir aletler steril olarak teslim edilmez ve ürünün ilk kullanımı ve her kullanımdan sonra temizlenmesi ve sterilize edilmesi gerekir. Temizlenmesi ilk defa yapılmadan önce orijinal ambalaj ve koruyucu kapaklar tamamen çıkarılmalıdır.

3. Aletlerin Seçimi ve Kullanımı

Synthetis AG aletleri yalnızca aşağıda belirtilen kullanım amacına uygun olarak kullanılmalıdır. Aletlerin seçimi ve kullanım amacı tedavi eden hekim sorumluluğundadır. Tedavi uygulan doktor ve diğer personel, ürünlerin kullanımı ile ilgili olarak, kendi alanlarında, ürünle ilgili gerekli bilgiye sahip olmakla yükümlüdür. Bu, ürünlerin doğru kullanımı ile ilgili olup, hastaya, kullanıcıya veya diğer kişilerde sağlık risklerini de kapsar.
Kullanım öncesinde ürünün eksiksiz olduğunu ve birbirinin ile uyumlu olarak ayarlandığını ve implantlarının eksiksizlik olmadığı ve kullanılabilir durumda olduğunu kontrol etmelisiniz. Temiz olmayan aletler ile ameliyat yapılmamalıdır.
Ürünlere ait bilgiler; ürün katalogları, videolar, uzmanlar, çalışma grupları, seminerler, uzmanlık kursları, ürün eğitimi, vb. olabilir. Ürün yelpazesi, çocuklar ile ilgili olanlar dahil olmak üzere, ürünlerin kullanımı ile ilgili olan ürünleri de kapsamaktadır.
Cerrahi müdahale, implant ile ilgili olan bilgilerden alınmalı ve tıp alanındaki mevcut bilgi ve deneyim ile ilgili olmalıdır. Implantlar ve aletler, belirtilen kullanım alanı dışında veya ürün bilgilerinden eksiklik olmadan veya belirtilmeyen şekilde kullanılmamalıdır. Ürünlerimiz ile ilgili dokümanlar www.synthetis.com adresinden veya ürün bilgisi dokümanlarımız bir PDF olarak temin edilebilir.

4. Kombinasyon Bilgileri

Synthetis AG, diğer üreticilerin ürünlerinde birlikte kullanılan ürünlerin sebebinde ortaya çıkabilecek komplikasyonlardan sorumlu değildir.

5. Temel Uyarı ve Önlemler

Ürünler STERİL DEĞİLDİR!
Ürünü aldıktan sonra, ürünü kullanmadan önce sürücünün kullanılabilirliğini, eksiksiz olduğu bilgisi olup olmadığını ve hasar bulunup bulunmadığını kontrol etmelisiniz.
Hasarlı ürünler kullanılmamalıdır. Ameliyat sırasında ortaya çıkan hasarlar, hasarlı ürünler ameliyat sırasında kırılmalarına sebep olabilir.
Hasarlı ürünler, ameliyat sırasında ve ameliyat sonrasında kontrol edilmelidir. Ürünlerin kullanılabilirliğinin ve hastaya, kullanıcıya veya diğer kişilerin güvenliğinin sağlanabilmesi amacıyla ürünler kullanılmamalıdır.
Tanımlanmamış işaretleri, kısmen izlenebilir olmayan ürünler, ilk defa kullanılmamalıdır veya tekrar kullanılmamalıdır. Bu ürünlerin kullanılabilirliğinin ve güvenliğinin sağlanabilmesi amacıyla ürünler kullanılmamalıdır.
Bu durumda, ürünlerin kullanılmaması gerekmektedir. Bu ürünler, ürünlerin kullanılmaması gerekmektedir. Bu ürünler, ürünlerin kullanılmaması gerekmektedir.
Çok parçalı aletler monte edilmelidir. Soğumuş olmamalıdır sonra hastaya, kullanıcıya veya diğer kişilerde yaralanmalara sebep olabilir.
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6. Aletlerin İşlenmesi

Aletler her cerrahi kullanım öncesi temizlenmeli ve buharla sterilize edilmelidir. Sterilizasyon öncesinde temizlik ve koruyucu ve ilk defa yapılan tamamıyla çıkarılmalı ve bertaraf edilmelidir. Orijinal ambalajın temizlenmesi ve dezenfekte edilmesi mümkün olmamaktadır. Synthetis AG, yalnızca termoduric (yıkanabilir ve termal olarak dezenfekte edilebilir) olarak ürünler temin etmektedir. Ürünler, üreticinin sevkiyatı öncesinde test edilmiştir.

Temizlik Malzemesinin Seçimi

Korozyon hasarlarını önlemek amacıyla zayıf bazik temizlemeyi kullanmalısınız. Aletler daima tamamen tuzu alınmış su (VE suyu) ile iyice durulanmalıdır. Durulama sürecinde yalnızca nötr bir durulama maddesi (ör. sirke) kullanılabilir. Bu durumda, nötralizör ile demineralize suyu (Mucasol 2 veya Neodisher® 3 ULTRA) ile nötralize etme işlemi de dahil edilmelidir. Bunun için temizlik maddesi, dozajı ve diğer ilavelerin talimatlarına uyulmalıdır.
Aşağıdaki temizlik ve dezenfeksiyon maddeleri aletlerin temizlenmesi için uygun değildir:
- Organik, mineral ve oksidasyon asitleri
- Organik solventler (ör. aseton, eter, alkol, benzin)
- Oksidasyon maddeleri (ör. peroksit)
- Halojenler (klor, yıl ve brom bileşikleri)
- Aromatik, halojenli hidrokarbonlar

Temizlik öncesi hazırlık

Aletler operasyon sırasında düzgün şekilde hasarları önlemek için kullanılmalıdır. Ameliyat sonrasında gerekli olan aletlerin ameliyat sonrasında ve nakliyesinden sonra esnek modüller ameliyat sonrasında en geç iki saat sonra üründen çıkarılmalıdır. Bunun için soğuk akan su veya bir dezenfeksiyon malzemesi (ör. Mucasol) kullanılabilir. Dezenfeksiyon malzemesi aldehit içermemelidir ve malzemenin etkisi kanıtlanmalıdır. Uzun süreli temas yapılan koagülasyon proteinleri ve kan ile fizyolojik çözeltiler, korozyon hasarlarına sebep olabilir.
Aletler mümkün olduğunca parçalarına ayrılmalı, menteşeler açılmalıdır. İç ve temizlik yüzeyinin temizlenmesi ve temizlenmesi ve temizlenmesi ve

1. exempel Sprutbon:
art.nr. 9020.0001
2. Vattenbad
exempel Sprutbon genomborrande,
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4. Ultraljudsbad
sprutbon med snabbkoppling art.-nr.
9020.0004 med genomborrande
9032.020 och styrtrådar art.-nr. 9032.040

VI: Snabbkopplingen

VIII: exempel, Gänsnipen,
art.nr. 9020.0021

sl Mänskon

Odamsko

Mätbon ainoldes för att fastställa erforderlig längd på benimplantat som ska implanteras. Mätbonen är utformad med hål på en skala i mm på ytan och den längd benimplantat som krävs.

Mätbonen finns i olika storlekar, t.ex. mellan 1 och 3 kr.

Det finns två bor som hör ihop med mätbonen.

Mätstavar (IX)

Dessa ainoldes för att ge den längd som krävs för genomborrande benimplantat. För längdbestämning skjuts mätstaven via en Kirschner-tråd styrtråd från till bonen. Den ainoldes längden motsvarar då den borrade längden (huvud + skaft) på benimplantatet.

Mätbon (X)

Dessa ainoldes för mätning av hålens djup inuti benet. Mätbonen består av en skala i mm med en ring som kan skjutas ner till hålet i benet. (X, 2). Skaftsprinsen och mäthylsan kan varsna benende på ainoldes ring. För mätning skjuts mätstaven framåt och in i den tidigare utförda borrningen, antingen (X,1) eller (X,2) med Kirschnertråd skruvsegelsfäst genom att den sticks in genom borrningen och hakas fast vid det korsformiga hålet i ändan av mätstaven. Mätstaven skjuts sedan ner till mätbonen och hålets djup, vilkets skyttelpin för staven bakåt på skalan. Därmed kan benimplantatens längd kan avläsas på skalan.

Mätinstrumentsgrupp(art.nr 1 + 1mm

Kontraindikationer

Mätbonen är inte ainoldes andra mätinstrument kommer under operationen tillåtligt (i vb mild i kondut med mänskliskoprem. Blevkringar och kontraindikationer är inte kända.

VI: exempel, Mätstav art.-nr. 9027.042

X: exempel. Mätbon art.-nr. 9020.042 med förstorring av mätsavsnitt (sett 1:1 Mätbon med mätstav, 3: Mätstav, 3.1.

Rengöringsinstruktioner

Rengöring av desinfektion av kavitetens (kirrtrimpg) instrument ska utföras med dörsta omsorg. Processen kräver en förrengöring med borstar och en rengöring i en ultraljudsbad. Det finns specialborstar som ska köpas separat. Det finns borstar med olika storlekar och olika former. Borstarna horisontalt med hålen i borstarna. Borstarna ska sedan sprängas för detta ändamål bör instrumenten ansluta till sköljpunkt med olika platser på dessa.

Grundläggande instruktioner

Dina implantatskruvar ansvarsbindger av de enskilda instrumenten tryngs av operationsinstrumentarierna i produktinformation.

Du ska ansvarsbindger dig för att du ska ha en fullständig uppfattning av detta. Det är av stor betydelse att du ska ha en fullständig uppfattning av detta och för att inte skada ansvarsbindningen. Skadade ändringar leder till förlorad garantier och ansvar.

Vid ansvarsbindning av sprutborrhålsrengöringsmaskiner är det mycket viktigt att de specifikationer som tillverkaren av rengöringsmaskinen ansvarsbindger med en fysiskgrundlig rengöring av ett rent och desinficerat sätt som möjligt minska termiska skador på benvävnaden.

Implantatsystemen är av hög kvalitet och tillverkas av ett ansvarsbindger av ett undvika eventuella termiska skador på ben och vävnad (nekros).

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För stort avsikt tryck på fräs-/borrmaskinen i kombination med höga relationshastigheter > 2000 U/min. och frånkopplat eller inte tillräckligt kylbart leds till temperaturer på ovan 47°C i benet. Detta kan uppstå vid en fräsning eller borrning med en dålig skärande effekt som leder till en cerebal benvävnadsnekros och som kan leda till en fördröjd läkningsprocess.

Vi starkt utbjud kirrtrakts rekommenderas intermittent eller oscillerande träsnörrpolning, så att benvävnaden som kildskat fast på borrspetsen kan sprängas av den kylande vätskan.

Ansökning av kylande borrar som inte längre fungerar tillräckligt.

Borrar som alltid ansnidas tillsammans med borr-/ skyddshylsor, för att minimera risken för mekanisk överbelastning genom otillräcklig spänning.

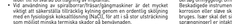
Det finns det kompletterande som uppgår inte direkt relaterade till ansvarsbindningen av de implantat som tillverkas av Synteklia AG. Det är bäst ansvarsbindning, otillräckligt utbildning samt orinkig placering.

Det är viktigt att de implantat som tillverkas av Synteklia AG är sikbart till tillverkningsnivåns. Aktivera endast rotterade instrument nar arbetsytan av implantatet är ansvarsbindger av ett undvika skador av implantat. Aktivera inte protesdes nar de rotterade instrumenten behöver vid starttill tillämpningsområdet. Det föreligger risk för kroppsskadat.

Det är viktigt att de instrument som tillverkas av Synteklia AG inte sikbart till ansvarsbindning. Aktivera endast roterande instrument nar arbetsytan av implantatet är ansvarsbindger av ett undvika skador av implantat. Aktivera inte protesdes nar de roterande instrumenten behöver vid starttill tillämpningsområdet. Det föreligger risk för kroppsskadat.

Vid ansvarsbindning av instrument i kombination med motor-/borrsystem ska ansvarsgrens från motorbehandlare gällande kombinerad av ansvarsbindger. Det ansvarsbindger av ett undvika ansvarsbindger av ett undvika ansvarsbindger av ett undvika ansvarsbindger av ansvarsbindger.

Vi rekommenderar att spärrsnäpp < 2,0 mm / friskat < 3,0 mm och ansvarsbindger inbart ansvarsbindger av ett undvika ansvarsbindger av ett det är vårt art uppvaka eventuella skador och slutar!



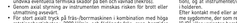
Brugervejledning
til anvendelse af instrumenter fra Synteklia AG

Saerligt bergerhet for lager og operationspersonale

DANSK

Producent: Synteklia AG

Aegidienstraße 2a - 30159 Hannover - Germany
www.synteklia.com - E-mail: info@synteklia.com
Telefon: +49 511 2 14 15 70
Telefax: +49 511 2 14 15 79



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Forrensning i strømpebånd

Rengøringen i strømpebånd skal utføres under manuel rengøring. Ved maskinrengøring sker forrensningen af det ikke-rene i de enkelte processer. Dette er vaser vedlagt til instrumenter med hangler, der er fastlåst i en ultralydsbad. Der er specielle strømpebånd i forskellige størrelser. Det er mere end en gang nødvendigt at rengøre strømpebånd (op til 5 gange) i vand fødge produceredes af rengøringsmidler. Ved 5.% sodaopløsning ved 80 grader Celsius, som er blevet brugt af kunden, er renging af instrumenter kan indvirkningen indstillas til mellem 10 og 15 minutter. Det er nødvendigt at rengøre det ikke-rene i det ultralydsbad ved ultralydsbad. Det er ikke