

GET BETTER

with CiproScrew™ you will



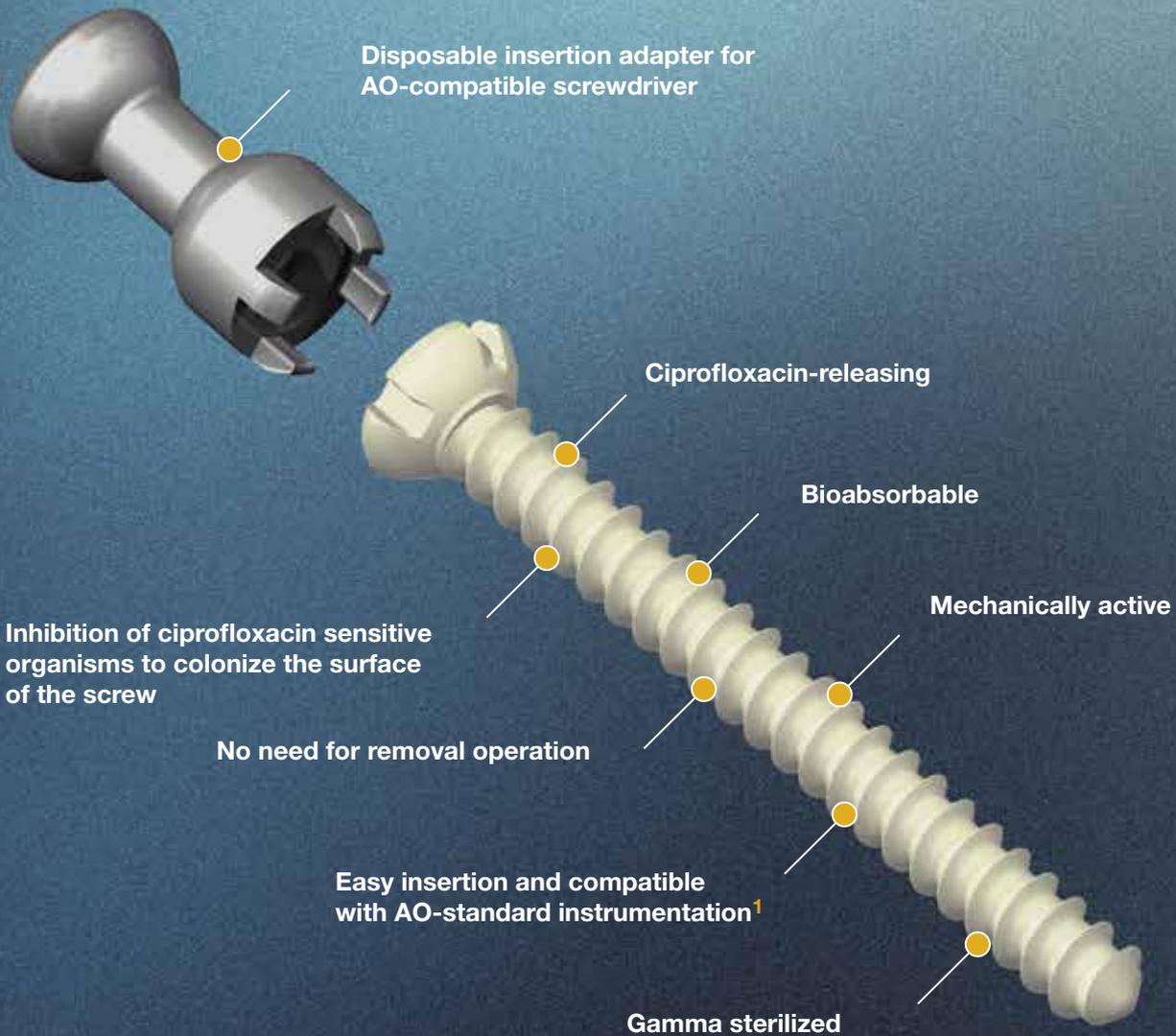
The world's first bioabsorbable bone fixation device with long term drug release - CiproScrew™

www.bioretec.com

bioretec

GET BETTER with CiproScrew™

To prevent implant related infections

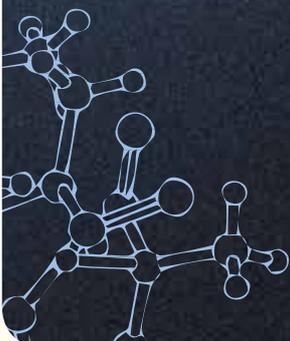


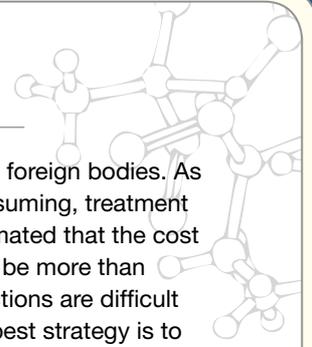
Ciprofloxacin

Ciprofloxacin is a bactericidal fluoroquinolone antimicrobial whose mechanism of action is the inhibition of DNA gyrase. Ciprofloxacin has a broad spectrum of activity against a wide range of Gram-positive and Gram-negative bacteria including the most common implant-related infection causing bacteria, *S. aureus*, *S. epidermidis* and *P. aeruginosa*.

Ciprofloxacin is evenly dispersed throughout the CiproScrew™. It is released from the screw within approximately 30 to 36 weeks.

¹ AO/ASIF (Arbeitsgemeinschaft für Osteosynthesefragen/ Association for the Study of Internal Fixation) Standard ASTM F 543-07.





Risk of infection in orthopaedic surgery

Infection is a common serious complication of surgical procedures in orthopedics, traumatology and thoracic surgery especially when traditional fixation implants are used. Although on average, only a few percent of inserted fixation devices become contaminated and cause infection, in the case of open fracture, the incidence of infection may exceed 30%. Several factors which increase the risk of such infection include smoking, diabetes, age, or an immunocompromised state. (1,2,3,4)

The treatment of implant-related infections is very challenging and time consuming. The most common treatments involve long term systemic antimicrobial therapy,

surgical debridement and removal of all foreign bodies. As well as being challenging and time consuming, treatment is also very expensive. It has been estimated that the cost of managing surgical site infection may be more than \$30 000 per case. (5,6) Since such infections are difficult to cure and expensive to manage, the best strategy is to prevent infections in the first place.

By introducing the world's first antibiotic releasing bio-absorbable bone fixation screw – CiproScrew™ Bioretec offers a solution to prevent implant-related infection.

For prevention of local infection – CiproScrew™

In addition to its fixation function, CiproScrew™ is designed to inhibit ciprofloxacin sensitive organisms to colonize the surface of the screw when implanted in the body. When placed on a bacterial culture*, the bactericidal effect of CiproScrew™ can be seen as a bacteria free clear area around the screw.



Conventional Screw



CiproScrew™

In preclinical investigations CiproScrew™ showed local ciprofloxacin release around the implant and effective prevention of implant related infection caused by *S. aureus*. Typical signs of implant-related infection were not seen with the CiproScrew™ as were seen with the metallic screw.(7)



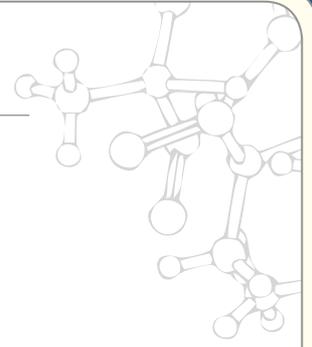
CiproScrew™



Metallic screw

Fixation of tibiofibular syndesmosis

**S. aureus* (ATCC 25923)
after 18 h incubation at 35°C.



For stable fixation of bone fractures – CiproScrew™

CiproScrew™ is indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures in the presence of appropriate immobilization when infection by ciprofloxacin sensitive organism is a potential risk. As the operated bone fracture or osteotomy gains strength during healing, CiproScrew™ gradually loses its strength, however, maintaining its function for at least 8 weeks. Bioabsorption of the screw takes place within approximately two years. In clinical investigation, CiproScrew™ showed an equal clinical outcome and safety profile as metallic standard screw used in ankle syndesmosis fixation.⁽⁸⁾

For easy and aseptic use – CiproScrew™

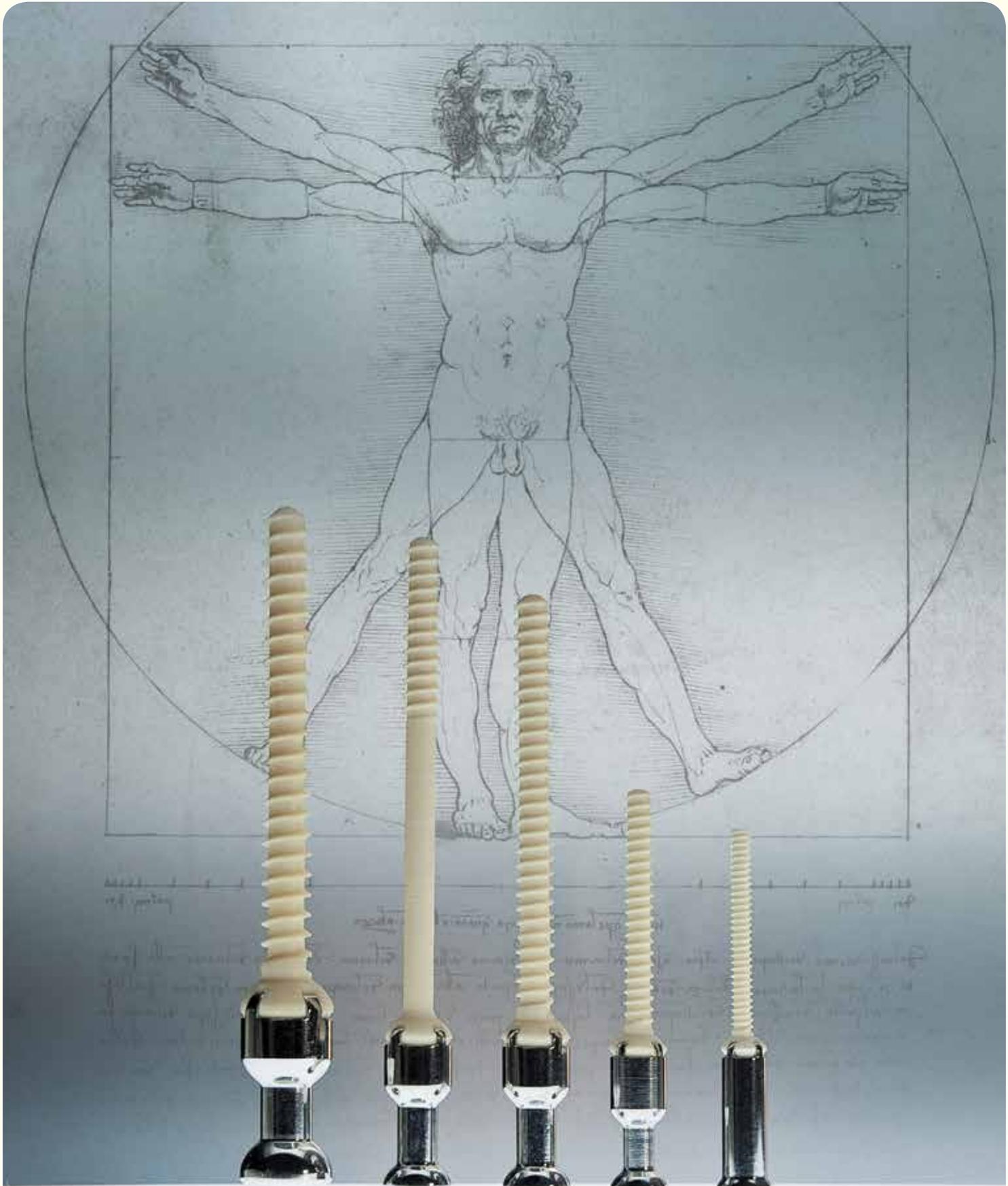
CiproScrew™ is delivered inside the holder. Because of disposable insertion adapter connected to the head of the screw, CiproScrew™ is easy to pick from the holder using an AO-compatible screwdriver. This supports an aseptic way of working during the surgery.



Similar design to Bioretec's ActivaScrew™ product family

- Unique AutoCompression™ feature reduces the risk of unstable fixation
- High strength properties
- Easy insertion
- Safe medical use
- No need for removal operation
- Supplied as gamma sterilized
- Compatible with AO-instrumentation

CiproScrew™ opens up new possibilities to prevent implant-related infection which may occur with traditional fixation products used in orthopedics, traumatology and thoracic surgery. It is the first drug-releasing bioabsorbable fixation screw in the world and there is more to come from Bioretec.



Bioretec products have their roots in research on biomaterials and implant technology started by the team led by Professor Pertti Törmälä at the Tampere University of Technology in 1977; which was first in the world.

So far, millions of patients have benefited of earlier innovations of our key people. Bioretec's products are developed under customer guidance to fulfill the highest demands of safety, user-friendliness and cost-efficiency.

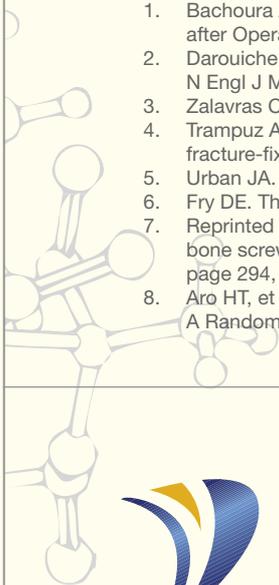
Bioretec is devoted to supply solutions, which satisfy surgeon requirements and benefit patients. Financially feasible and responsible materials are the top priority and an essential part of the high-tech solutions we offer.

Implants that do more – It's Bioretec

www.bioretec.com

References:

1. Bachoura A, et al. Infirmity and Injury Complexity are Risk Factors for Surgical-site Infection after Operative Fracture Care. Clin Orthop Relat Res 2010 Dec 16. [Epub ahead of print]
2. Darouiche RO. Treatment of Infections Associated with Surgical Implants. N Engl J Med 2004;350:1422-9.
3. Zalavras CG, et al. Management of Open Fractures. Infect Dis Clin N Am 2005;19:915-929.
4. Trampuz A and Zimmerli W. Diagnosis and treatment of infections associated with fracture-fixation devices. Injury 2006;37:S59-S66.
5. Urban JA. Cost Analysis of Surgical Site Infections. Surgical Infections 2006;7:S19-S22.
6. Fry DE. The Economic Costs of Surgical Site Infection. Surgical Infections 2002;3:S37-S43.
7. Reprinted from Bone, 36(2005), T.J. Mäkinen et al., Efficacy of bioabsorbable antibiotic containing bone screw in the prevention of biomaterial-related infection due to Staphylococcus aureus, page 294, Copyright (2004), with permission from Elsevier.
8. Aro HT, et al. Fixation of Ankle Syndesmosis by Antibiotic Releasing Bioabsorbable Screw: A Randomized RSA Trial. 23rd European Conference of Biomaterials 11.9.-15.9.2010.



Manufacturer
Bioretec Ltd.
Hermiankatu 22, Modulight Building
FI-33720 Tampere, Finland
Tel. +358 20 778 9500
Fax +358 3 317 0225
sales@bioretec.com
www.bioretec.com

Distributor