

Bucharest 2-4 October
2025



Update on the implantable device

S.Crimaldi

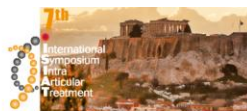
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N **Summary** **NETFLIX**



Athens
5-7 October 2023

**The Intra-articular residence time of
products: an unmet need**

Sergio Crimaldi

SIMPOSIO NAZIONALE ANTIAGE
Associazione Nazionale per lo Studio e la Cura dell'Artrosi

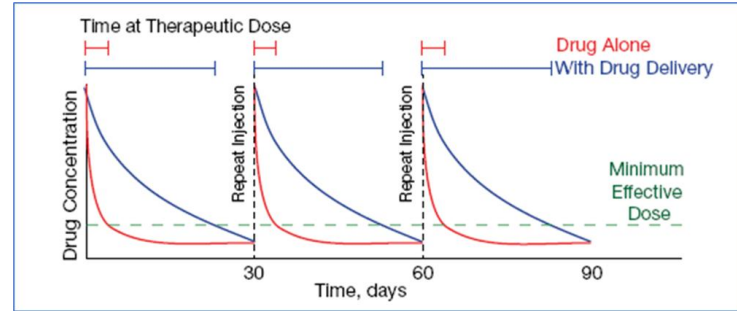
ROMA, 1-2 ottobre 2024

**Un nuovo approccio nella
terapia intra-articolare:
la somministrazione continua tramite
catetere**

Sergio Crimaldi

Actually

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Assumption: The known technique has some important limits

For the Doctor

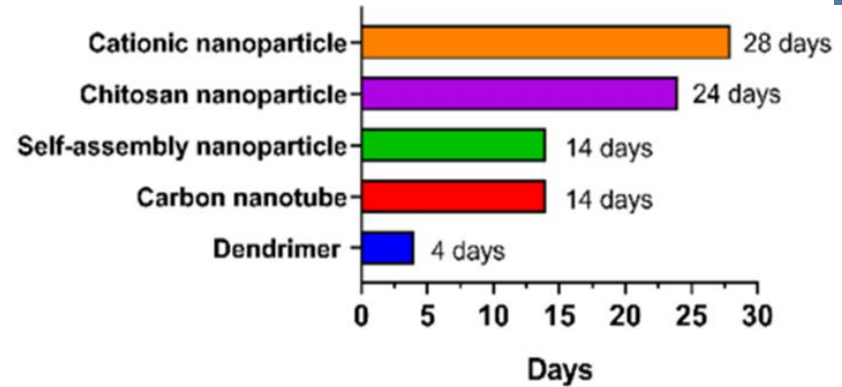
- ▶ difficult to adjust dosage
- ▶ Discrete and non-continuous quantities
- ▶ It is not possible to **instantly** modulate the therapy according to the effect, even if **necessary**.

For the Patient

- infiltration, in general, must be performed periodically and only by specialized health personnel.
- Therefore a patient is fine after an infiltration but, time by time, he sees the effect of the drug vanished.
- He is therefore forced to return frequently to hospitals or clinics.

What can we do ?

- Greater volume/concentration of products: risk of more side effects
- Greater molecules: more attack from immune system, less clearance through synovial membrane and vessels
- Smaller molecules: the opposite
- Add carriers: nanomaterials, microspheres, drug delivery systems, matrixes. Often «rubbish» in intercellular space or inside cells
- Associations: other drugs that limit clearance or inflammation → long and costly way (new drugs)



[Intra-articular targeting of nanomaterials for the treatment of osteoarthritis.](#) Brown S, Kumar S, Sharma B. Acta Biomater. 2019 Jul

[Intra-articular drug delivery: the challenge to extend drug residence time within the joint.](#) Edwards SH. Vet J. 2011 Oct

[Recent advances in targeted drug delivery for treatment of osteoarthritis.](#) Mehta S, He T, Bajpayee AG. Curr Opin Rheumatol. 2021 Jan

[Targeted delivery to cartilage is critical for in vivo efficacy of insulin-like growth factor 1 in a rat model of osteoarthritis.](#) Loffredo FS, Pancoast JR, Cai L, Vannelli T, Dong JZ, Lee RT, Patwari P. Arthritis Rheumatol. 2014 May

[Cartilage penetrating cationic peptide carriers for applications in drug delivery to avascular negatively charged tissues.](#) Vedadghavami A, Wagner EK, Mehta S, He T, Zhang C, Bajpayee AG. Acta Biomater. 2019 July

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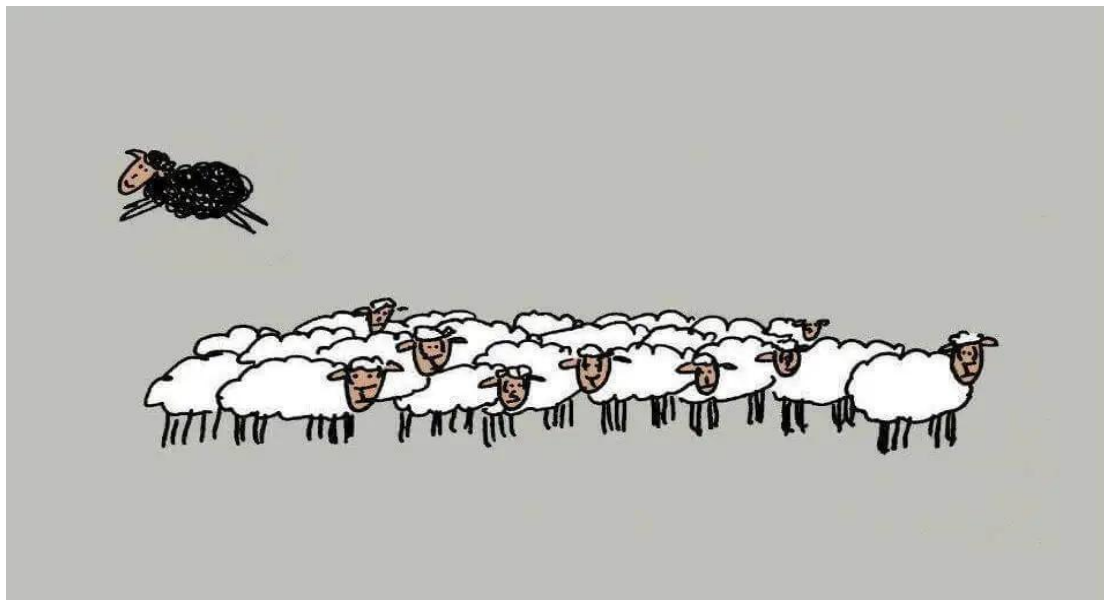
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Can we do more?



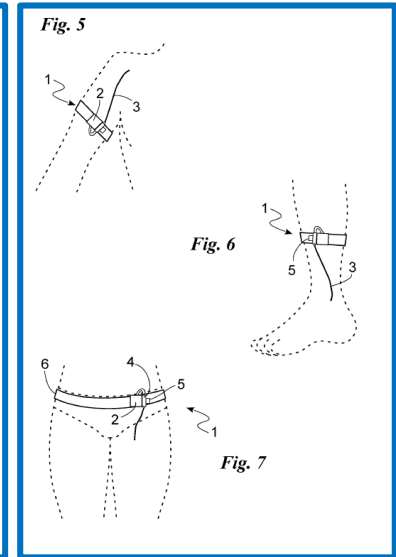
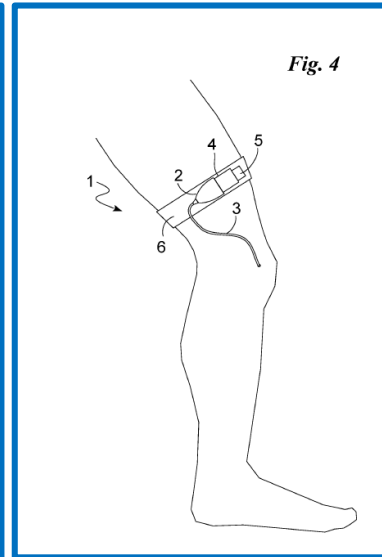
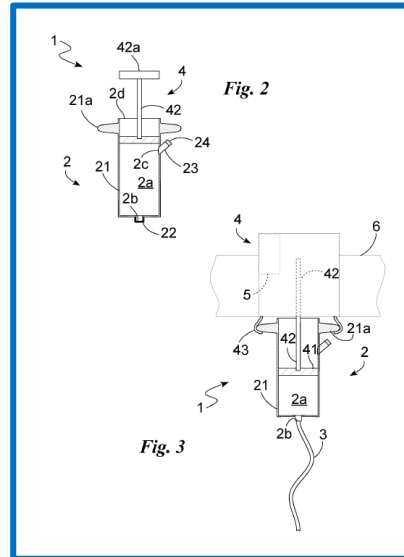
Give what we have ... in a different way ...



What is it about ?

- Class IIb continuous articular infusion device
- Miniaturized
- Wearable

A Class IIb medical device belongs to the category of medium-high risk devices, which includes long-term invasive devices, implantable devices (including those partially or totally absorbed by the body), and active devices with potentially dangerous interactions with the body.

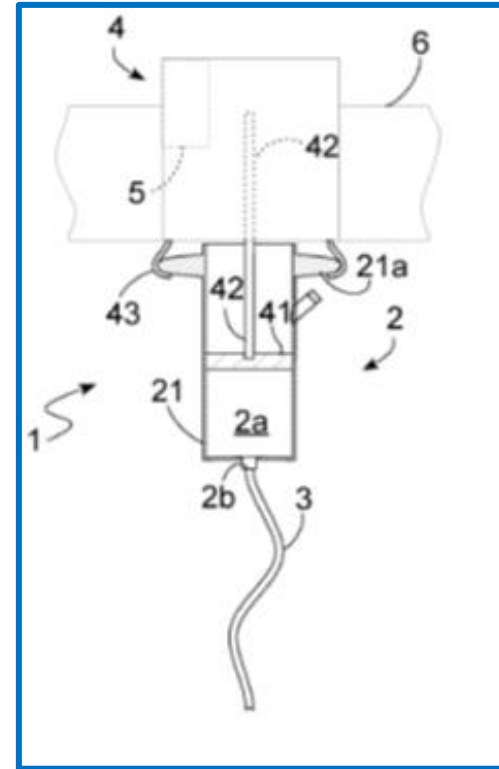




How it's made

Composed of 2 parts:

- **An electromechanical part**
 - Programmable 'on board' or with dedicated 'app'
 - Mechanical propulsion.
- **A sterile consumable part**
 - Tank (which also provides perforated access)
 - Infusion set (catheter)

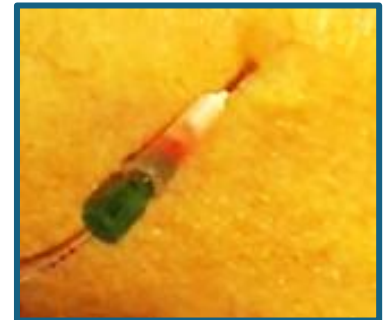


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Some details ...

- The catheter can be inserted through a 18G needle
 - Common steril medication like for butterfly fixing
 - Knee: In the overpatella space (no load space)
 - A Velcro band with a bag fixes the pump to the patient
- } No need for a surgery room
- } No need to sit still during infusion



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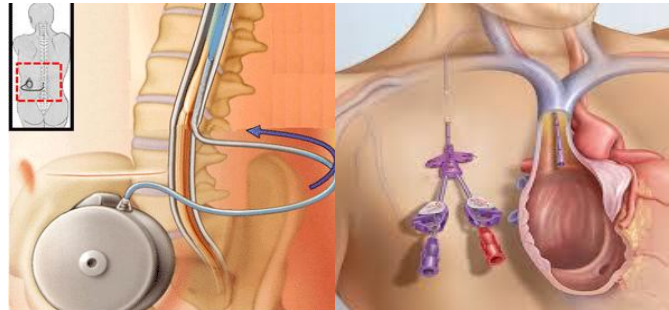


Permanent catheterism

It is already widely used for:

- antalgic therapy → epidural
- insulin therapy → subcutaneous
- Chemotherapy → endovenous

Currently there is no device dedicated to joints.



Advantages of the articular device:

- Prolonged therapies for days (from few hours to XX days);
- Simple and minimally invasive answer to a complex problem: ensuring the correct dose and prolong the articular resident time of drugs;
- Avoid the use of crystals/nanomaterials for "depo" drugs;
- Instantaneous modulation of administration (slower or faster in a specific moment);
- Transportable and wearable: reduction of the need for hospitalization → device that can be used for Home Care.



Disvantages of the articular device:

- Infections?
 - Comparable to other catheterism.
 - *Dawson reviewed the literature and found rates of deep infection ranging from 0% to 0.7% (Λif no medication applied)
 - The same device can be used to give antibiotics
- Others related to wrong use
- malfunctions
- Other minor issues: listed for supervision o medical devices



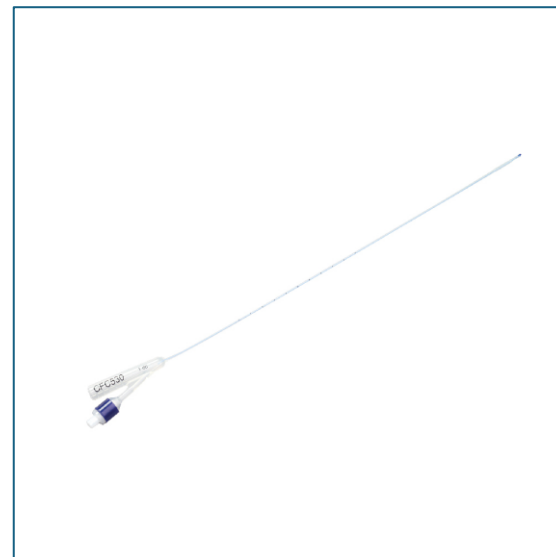
*S.J. Dawson,
Epidural catheter infections
Journal of Hospital Infection
Volume 47, Issue 1, 2001, Pages 3-8,
ISSN 0195-6701,
<https://doi.org/10.1053/jhin.2000.0872>.

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- **Antibiotic-impregnated catheters::**
 - Impregnated with two antibiotics rifampicin and clindamycin;
 - They have been shown to reduce colonization of gram-positive bacteria on all catheter surfaces;
 - A small amount of antibiotics carries a low risk of toxicity;
 - Very low risk of resistance mutation due to two antibiotics that are difficult to resist at the same time;
- **Catheters treated with Chlorhexidine**
- **Catheters structured with antimicrobial molecules that inhibit their colonization:**
 - BACATTACK project 2015 (A stealth attack tool for preventing clinical drug resistance through a unique self-regenerating surface), funded by UE



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New promising approach: anti biofilm

Chemistry & Biology



Volume 9, Issue 8, August 2002, Pages 873-880

Review

Antibiofilm Approaches: Prevention of Catheter Colonization

Paul N Danese  

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[https://doi.org/10.1016/S1074-5521\(02\)00192-8](https://doi.org/10.1016/S1074-5521(02)00192-8) 

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“Catheter-impregnated antibiofilm compounds that render pathogenic microbes incapable of attaching to the catheter surface”

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Antibiofilm strategies to prevent catheter colonization include impregnating catheters with bactericidal agents (like antibiotics or antiseptics) to kill pathogens, using non-bactericidal antibiofilm agents that prevent microbial attachment to the catheter surface, applying antibacterial coatings or specialized biomaterials that scavenge nutrients like iron, and utilizing biofilm-disrupting molecules like enzymes that break down the biofilm matrix. Research is also ongoing for novel approaches such as [photodynamic therapy](#) and other [biofilm-targeting molecules](#) to enhance prevention and treatment efficacy.

Bactericidal and Bacteriostatic Approaches

Antimicrobial Impregnation: Catheters can be impregnated with antimicrobial agents (e.g., silver, nitrofurazone, chlorhexidine) to elute from the device and kill bacteria and fungi, preventing their growth and subsequent biofilm formation.

N-acetylcysteine (NAC): This antibiofilm agent, sometimes used in combination with antibiotics, has shown promise in vitro for disrupting bacterial adhesion and biofilm formation on catheters

Novel and Emerging Technologies

Biofilm-Targeting Molecules: Research is exploring small molecules, peptides, and other substances that interfere with bacterial signaling pathways ([quorum sensing](#)) or specifically target and disrupt biofilm components.

Photodynamic Therapy (PDT): This method uses a photoactive dye that, when activated by light in the presence of oxygen, can kill bacteria on and within biofilms, offering a localized, non-antibiotic treatment approach.

Combination Therapies: Combining different antibiofilm strategies, such as combining an antimicrobial agent with an anti-adhesion compound or an EPS-degrading enzyme, can provide a more robust and durable effect against biofilm formation

Non-bactericidal Antibiofilm Agents

Anti-Adhesion Coatings:

These approaches modify catheter surfaces to inhibit the initial attachment of microbes, which is a crucial step in biofilm formation.

Iron Scavenging:

Creating catheter surfaces that bind essential nutrients, like iron, can prevent bacteria, such as *S. epidermidis* and *P. aeruginosa*, from utilizing these nutrients for biofilm growth.

Biofilm Matrix Disruptors:

These agents, such as enzymes like [Dispersin B](#) (DspB), target and degrade the extracellular polymeric substance (EPS) or "slime" that encases biofilms, allowing for dispersal or further breakdown of the biofilm structure.

What articular product ?

- Hyaluronic acid
- Anaesthetics
- Cortisone (no retard)
- **Antibiotics**
- Bisphosphonates (currently under study)
- Regenerative medicine products (PRP, etc.)





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What joints?

- Described in the patent.
- Main joints:

Knee

Shoulder

Hip

Ankle

Elbow

Wrist

What pathologies ?

All joint pathologies, acute or chronic, primitive or secondary.

Example:

- Osteoarthritis
- Arthritis
- **Joint infections**
- Algodistrofia (solves DH problems)
- Post surgery (e.g. arthroscopy)

Numerical order of potential patients: **hundreds of millions**

Who can use the device?

- Orthopedic
- Rheumatologists
- Interventionist radiologists
- Physiatric drs.
- Infectious disease specialists
- Sports doctors
- Infiltrator doctors (in Italy also family doctors)
- Researchers



... Everyone that can do an arthrocentesis

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Perhaps we can address 2 problems of infiltrative therapy:

- ... We have good drugs but perhaps given in the wrong way and therefore less effective than they might be**
- ... Extremely slow, difficult and expensive to develop new molecules or carriers**

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**No longer what to give but how to give what we
already have ...
Ready to use solution to test something different**



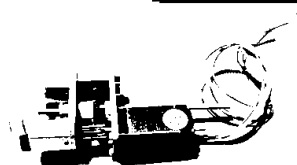
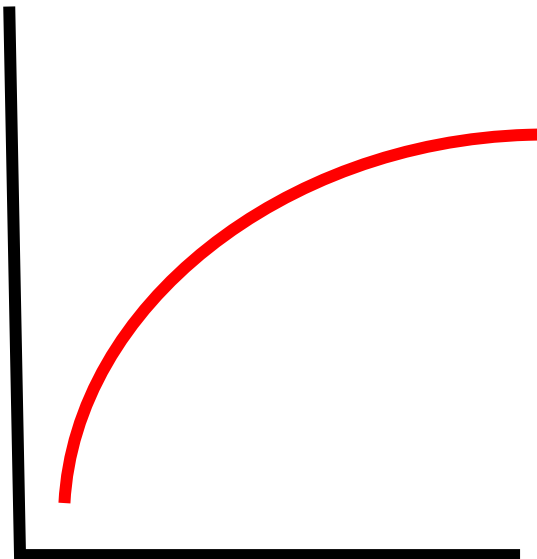
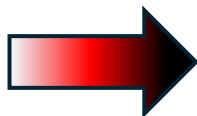
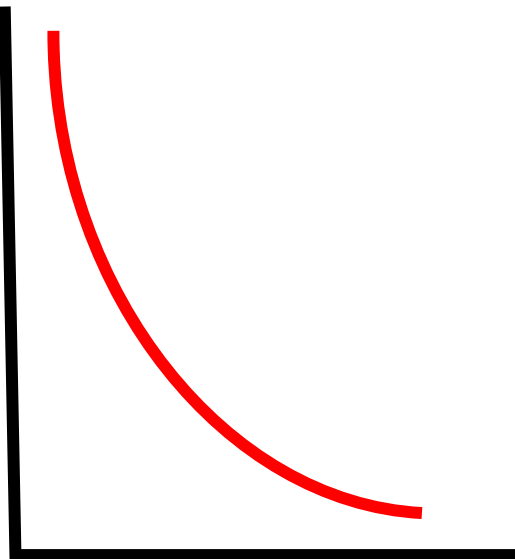
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Try to change a clearance curve in a steady state curve



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Visual summary

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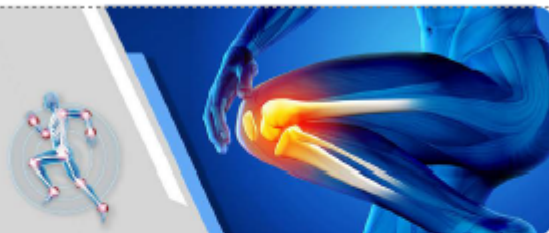
Volume 6 • Issue 3 | 198

fortune
Journals

Research Article

**JOURNAL OF ORTHOPAEDICS
AND SPORTS MEDICINE**

ISSN: 2688-5115



Maximizing Intra-Articular Therapy for Osteoarthritis and other Joint Diseases: Continuous Infusion Device for Prolonged Drug-Target Residence Time

Sergio Crimaldi^{1*}, Paolo Mario Sarais², Antonio Devito³, Alberto Migliore^{2,4}

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Some immediate possible use of the device

- Step after classic infiltrative therapy failure
- Commercial recovery of L.M.W. hyaluronic acid and short-half-life products
- Research laboratories for new drugs (stopping infusion if needed)
- Studies on ANTIBIOTIC dosages IN JOINT INFECTIONS (with PROSTHESES too)
- During initial POSTCHIURGICAL rehabilitation (if pain)
- Veterinary medicine ...



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Clinical tests



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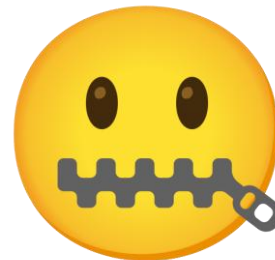
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Veterinary tests



The patent rights were purchased
by an important company
active in the veterinary field ...



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Contact for legal disclosure act to use or publish, availability, official clinical trials candidatures, collaborations



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Thank you

“I have a
dream”

Martin Luther Crimaldi
MARTIN LUTHER KING JR.



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Thank you