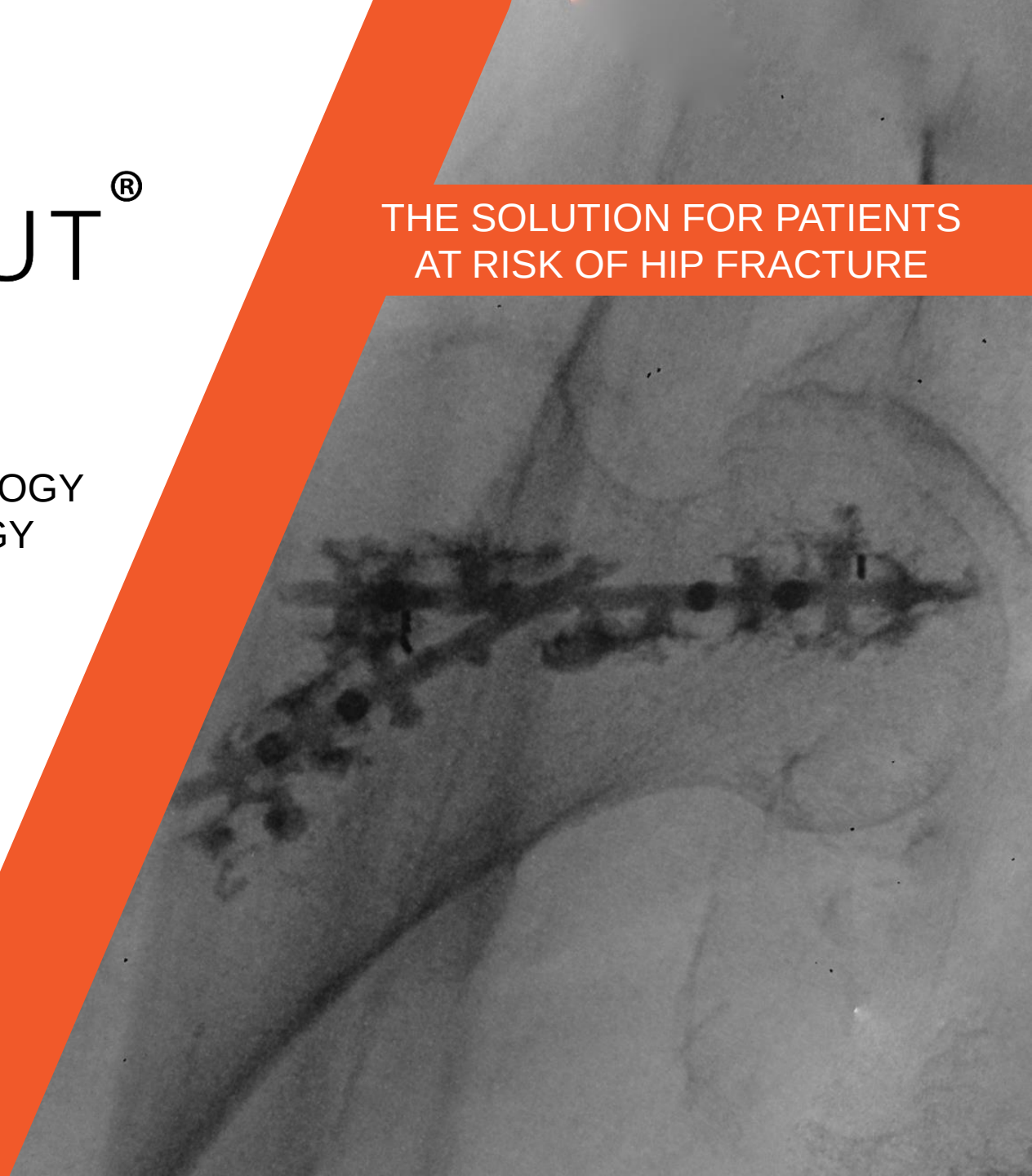
STRUT®

TRAUMATOLOGY
ONCOLOGY

hyprevention®

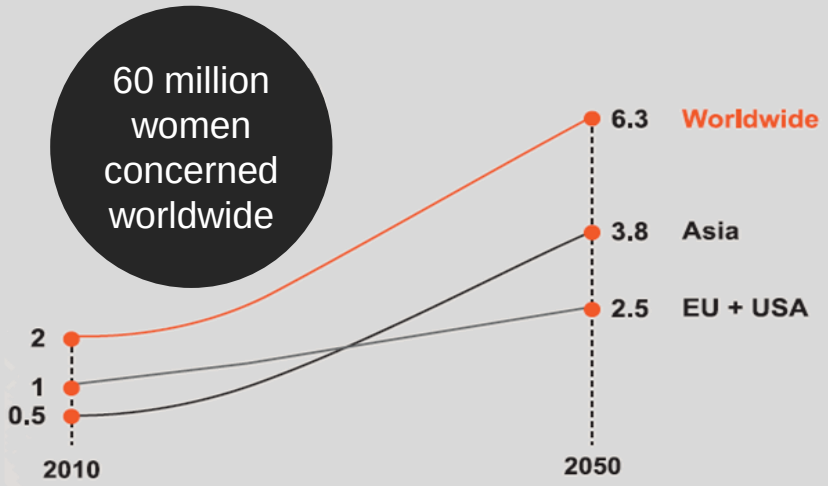
THE SOLUTION FOR PATIENTS
AT RISK OF HIP FRACTURE



HIP FRACTURE : A GLOBAL HEALTH ISSUE

TRAUMATOLOGY

More than 2 million hip fractures annually worldwide, over 6 million in 2050[1,2] with growing and aging population



- High risk of **contralateral hip fracture**
  - 9% at 1 year
  - Up to 20 % at 5 years[3]
- Serious **loss in quality of life** : chronic pain, reduced mobility and increasing of **dependence**[4]
- **Patients' mortality** 2-fold[3]
- High incremental **costs** for hip fracture treatment[5]

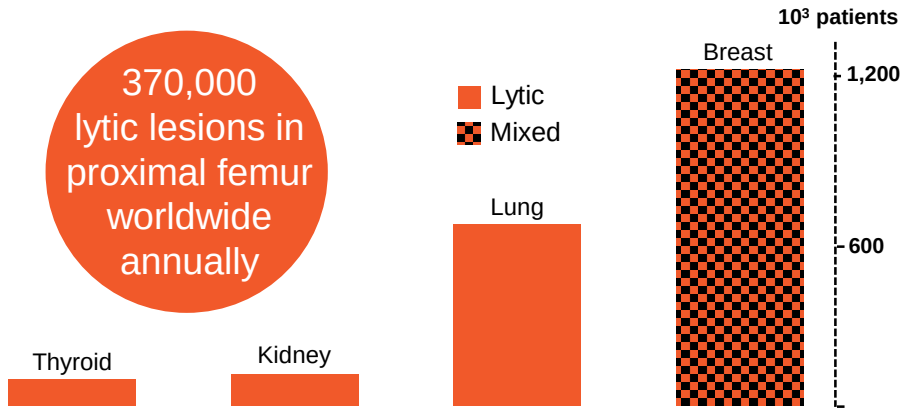
⇨ Surgical prevention : a potential solution to avoid contralateral hip fracture with associated morbidity and costs[6]

ONCOLOGY

25% of metastatic lesions occurs in the proximal femur, patients at high risk of pathological fractures[7]

- **Bone is the third location of metastases** after the lungs and liver. The origin of lytic bone metastases varies and is often linked to a primary tumour of the thyroid, kidney, lung or breast[7]
- Severe consequences of pathological fractures : **patients' life expectancy affected** and **loss of quality of life**[8]

⇨ Various surgical techniques, like standard osteosynthesis fixation, are being performed to treat lytic bone lesions, prevent these fractures and improve patients' quality of life[9]



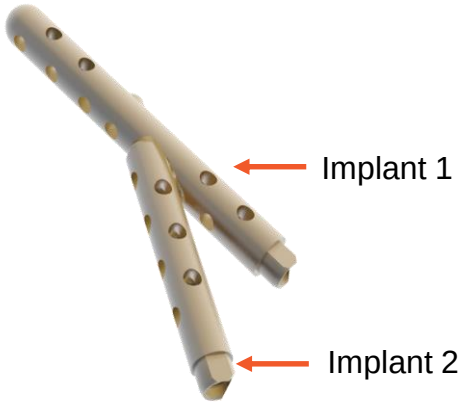
Bone metastasis incidence per type of cancer[10,11,12]

Y-STRUT® by Hyprevention® is a solution for internal fixation of proximal femur for patients at risk of osteoporotic fracture or impending pathological fracture

hyprevention®

THE SOLUTION FOR PATIENTS AT RISK OF HIP FRACTURE

STRUT®
Implant



Class II b

Patented

CE 1250

An implantable medical device composed of 2 implants connected in situ, made of radio-transparent PEEK polymer (results of biomechanical tests published[13])

Tantalum visualizing markers

A range of sizes is available to fit patients' anatomies :

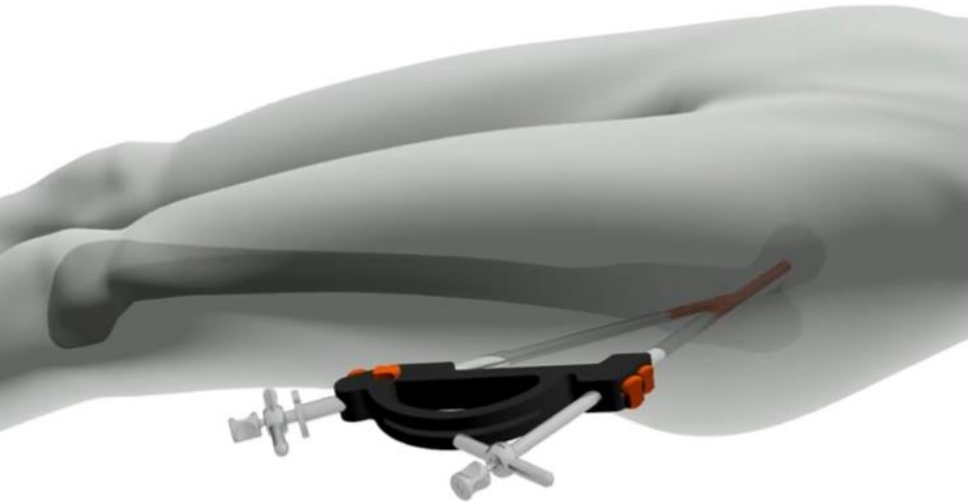
- **Implant 1** : ∅ 9 mm - 5 lengths (80 to 100 mm)
  To adapt to the **different lengths of the proximal femur**
- **Implant 2** : ∅ 8 mm - 6 lengths (55 to 80 mm)
  To adapt to the **different neck shaft angle**

Unique angle between implant 1 and 2

Cannulated implants with perforations to allow cement flow

Sterile packed implants

MINIMALLY INVASIVE PROCEDURE

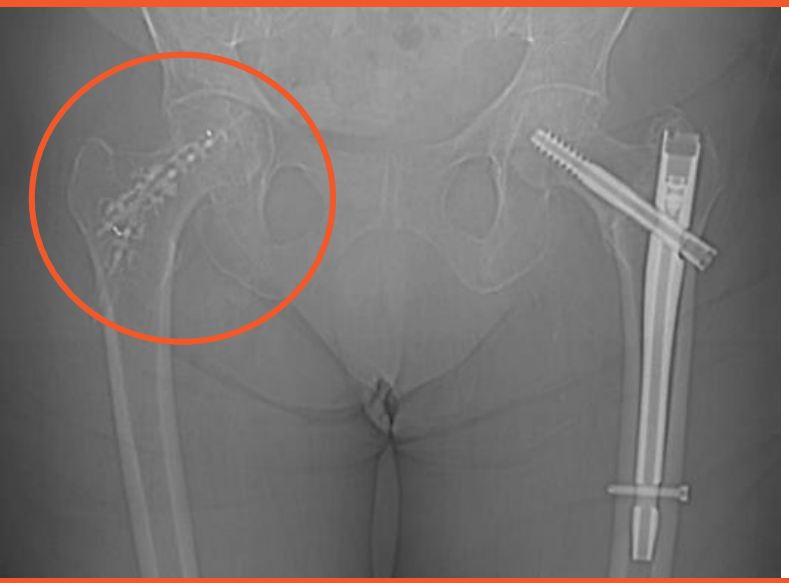


STRUT® is implanted by **minimally invasive procedure**

- **Pilot** allows **to assemble** safely the **two implants in situ** into the proximal femur
- Guidance is done under **imaging control**
- **Reusable instruments** set

hyprevention®

TRAUMATOLOGY INDICATION



STRUT® is indicated for contralateral percutaneous internal fixation of proximal femur, in patient with a low energy pertrochanteric fracture on the first side

- **Unique anaesthesia** for the fracture treatment and prevention procedure
- **No additional hospitalization and no rehabilitation** to the ones needed for the fracture treatment
- Combined with **PMMA bone cement** *(Low temperature of polymerization is recommended to ensure the bone anchoring of the device)*

CLINICAL EXPERIENCE

Woman, 80 years old
T-score : -2.7
Implanted by orthopaedic surgeon in the Emergency Operating Room, under general anaesthesia
Operating time skin-to-skin : 35 minutes
Combined with 6 cc of cement
No additional hospitalization stay

Two-years follow-up
Pain assessment VAS : 1
Functional assessment
OHS-12 : 43 – Satisfactory
No osteolysis
Good stability and osteo-integration of the implant

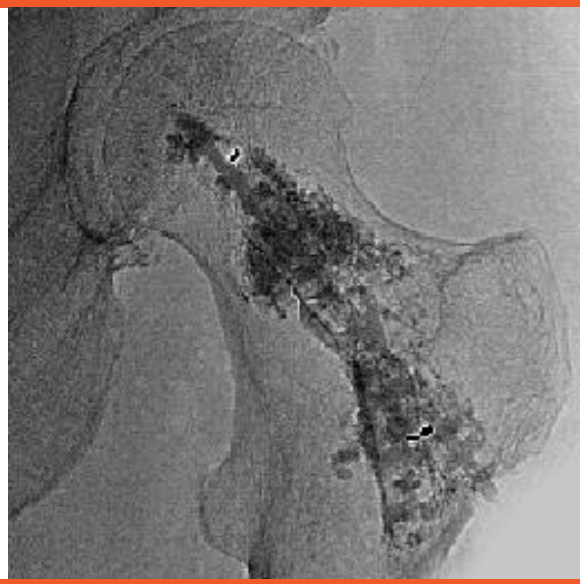
Woman, 82 years old
T-score : -3.8
Implanted by orthopaedic surgeon in the Emergency Operating Room, under general anaesthesia
Combined with 10 cc of cement
No additional hospitalization stay

Three-months follow-up
WOMAC score for pain : 5
WOMAC score for functionality : 3

ONCOLOGY INDICATION

STRUT® is indicated for percutaneous internal fixation for impending pathological fracture of proximal femur - act of last resort (ultima ratio)

- PEEK polymer material allows **local radiotherapy**
- Minimally invasive procedure allows to continue the **chemotherapy treatment**
- Combined with **PMMA bone cement** *(Injected in the needed quantity to fill the tumor. High temperature of polymerization is recommended to induce tumor cell necrosis)*



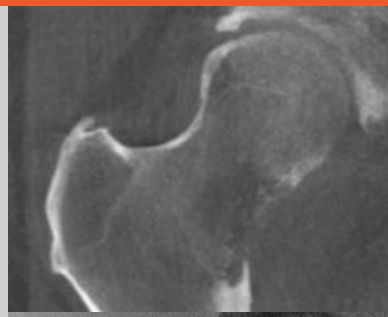
CLINICAL EXPERIENCE

Man, 52 years old
Mirels' score: 9
Lytic lesion of the femoral neck
Size of lesion ≈ 2/3 of the cortical thickness
Pain assessment VAS : 4
Implanted by interventional radiologist in the IR Operating Room, under general anaesthesia
Combined with 10 cc of cement
Discharged from hospital : Day +3

Two-months follow-up
Pain assessment VAS : 1
Functional assessment
OHS-12 : 24 – Moderate

Woman, 58 years old
Mirels' score : 9
Lytic lesion of the femoral neck
Size of lesion ≈ 1/3 of the cortical thickness
Pain assessment VAS : 4
Implanted by interventional radiologist in the IR Operating Room, under general anaesthesia
Combined with 10 cc of cement
Discharged from hospital : Day +1

Six-months follow-up
Pain assessment VAS : 3
Functional assessment
OHS-12 : 37 - Moderate



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CE 1250

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For more information, see the instructions for use.

The patient's written consent must be obtained before each implantation.

At the current stage, more clinical data are expected to confirm that the benefits outweigh the risks.

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